IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK Hon. Robert Kugler Hon. Joel Schneider **JURY TRIAL DEMANDED**

This document relates to: All Cases

MASTER LOSARTAN
MEDICAL MONITORING CLASS ACTION COMPLAINT

1. COME NOW the Medical Monitoring Class Plaintiffs ("Plaintiffs"), who file this Consolidated Amended Medical Monitoring Class Action Complaint ("Master Class Complaint")[1] against the below-enumerated Defendants.

I. INTRODUCTION

2. Plaintiffs bring this action on behalf of themselves and all others who consumed Defendants' generic losartan-containing drugs ("LCDs")[2] that were contaminated with an IARC- and EPA-listed probable human carcinogen known as N-nitrosodimethylamine ("NDMA"), and/or an IARC- and EPA-listed probable human carcinogen known as N-nitrosodiethylamine ("NDEA"), and/or an IARC-

[1] This is one of three master complaints being filed relating to Losartan in this multi-district litigation. The filing of three master complaints is to streamline the pleadings and issues for the parties' mutual convenience only. Class Plaintiffs do not waive any claims that are not raised herein, or that are asserted in another master complaint.

[2] All of the various acronyms used throughout this complaint are summarized in the glossary attached as Exhibit A hereto.

and EPA-listed probable human carcinogen known as N-Nitroso-N--methyl-4-aminobutyric acid ("NMBA") in the United States, and who thus suffered cellular damage, genetic harm, and/or are at an increased risk of developing cancer as a result, but have not yet been diagnosed with cancer. Plaintiffs seek injunctive and monetary relief, including creation of a fund to finance independent medical monitoring services, including but not limited to notification to all people exposed to this contamination, examinations, testing, preventative screening, and care and treatment of cancer resulting, at least in part, from the exposure to the NDMA, NMBA or NDEA contamination.

3. Losartan potassium and its combination therapy with hydrochlorothiazide are the generic versions of the registered listed drugs ("RLDs") Cozaar® and Hyzaar®, respectively. These RLDs are indicated for, inter alia, the treatment of high blood pressure, a condition affecting approximately 103 million Americans according to the American Heart Association.[3] Several million U.S. patients pay for (in whole or in part) and consume generic losartan each year.

4. According to testing by the Food and Drugs Administration ("FDA"), the LCDs at issue in this case contained NDMA, NMBA and/or NDEA at contamination levels that were in some cases hundreds of times higher than the

[3] https://www.heart.org/en/news/2018/05/01/more-than-100-million-americans-have-high-blood-pressure-aha-says.

FDA's February 28, 2019 interim limits for the impurities. The FDA has yet to release testing results for other impurities, including N-Nitroso-N-methyl-4-aminobutyric acid ("NMBA").

5. Upon information and belief, the reason Defendants' manufacturing process produced these compounds is linked to the tetrazole group that most angiotensin receptor blocker ("ARB") drugs, including losartan have. Solvents used to produce the tetrazole ring, such as N-Dimethylformamide (DMF), can result in the formation of drug impurities or new active ingredients, such as NDMA, NMBA and NDEA, as a byproduct of the chemical reactions.[4]

6. Similarly, the reuse of solvents (referred to as the use of "recovered" or "recycled" solvents), can also lead to the presence of nitrosamines in the drugs.[5]

7. Defendants have been illegally manufacturing, selling, labeling, marketing, and distributing the misbranded and/or adulterated LCDs in the United States since as far back as March 2012, when the FDA approved the first generic version of Cozaar and Hyzaar.

8. At all times during the period alleged herein, Defendants represented and warranted to consumers that their LCDs were therapeutically equivalent to and

[4] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001

[5] https://www.fda.gov/news-events/press-announcements/fda-provides-update-its-ongoing-investigation-arb-drug-products-reports-finding-new-nitrosamine

otherwise the same as their RLDs, were otherwise fit for their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

9. However, for years, Defendants willfully ignored warning signs regarding the operating standards at several of the overseas manufacturing plants where Defendants' generic LCDs were manufactured for import to the United States, and knowingly and fraudulently manufactured, sold, labeled, marketed, and/or distributed contaminated, adulterated, and/or misbranded LCDs for consumption in the United States.

10. Plaintiffs thus consumed Defendants' LCDs that were illegally introduced into the market by Defendants, exposing Plaintiffs to highly dangerous and potentially fatal carcinogenic substances. Defendants' conduct requires medical monitoring and constitutes negligence, defective manufacture, failure to warn, a violation of the Magnuson-Moss Warranty Act, breach of implied warranty of merchantability, breach of express warranty, fraudulent concealment, and other legal violations as set forth herein.

II. PARTIES

A. Class Representatives

11. The Master Complaints in this MDL relating to Losartan are divided among Personal Injury, Medical Monitoring, and Economic Reimbursement for

administrative purposes, as noted in Footnote 1. The below-identified Medical Monitoring Plaintiffs are absent class members in the Economic Reimbursement Class, and do not waive their status as absent class members by serving as proposed Class Representatives for the medical monitoring class or classes. Further, the parties below identified as Medical Monitoring Plaintiffs, in filing this Complaint, which is limited to medical monitoring per the administrative structure, do not waive, forego, or otherwise relinquish any entitlement they have to economic remedies for all harms alleged. Plaintiffs preserve their entitlement to any economic remedy for all harms alleged.

12. Plaintiff Samuel Rivera is a resident of the State of New Jersey. He was prescribed and used Losartan from approximately February 2012 to May 2019, at a dose of 100 mg per day. The distributors of Plaintiff's Losartan were Hetero, Hetero Labs, Hetero USA, Camber, Torrent Private, Torrent Pharmaceuticals, Torrent Pharma, and Walgreens, as defined below. This Losartan was contaminated with NDMA, NMBA, NDEA, or another nitrosamine. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiff will develop cancer.

13. Plaintiff Denice Gipson is a resident of the State of Missouri. He was prescribed and used Losartan from approximately May 2011 to December 2018, at a dose of 100 mg per day. The distributors of Plaintiff's Losartan were Hetero, Hetero Labs, Hetero USA, Camber, Torrent Private, Torrent Pharmaceuticals,

Torrent Pharma, and Walgreens, as defined below. This Losartan was contaminated with NDMA, NMBA, NDEA, or another nitrosamine. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiff will develop cancer.

14. Plaintiff Samella Jackson is a resident of the State of Arkansas. He was prescribed and used Losartan from approximately June 2018 to June 2019, at a dose of 50 to 75 mg per day. The distributors of Plaintiff's Losartan were Hetero, Hetero Labs, Hetero USA, Camber, Torrent Private, Torrent Pharmaceuticals, Torrent Pharma, and Walmart, as defined below. This Losartan was contaminated with NDMA, NMBA, NDEA, or another nitrosamine. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiff will develop cancer.

15. Plaintiff Rick Monchamp is a resident of the State of Arizona. He was prescribed and used Losartan from approximately February 2016 to September 2019, at a dose of 25 to 100 mg per day. The distributors of Plaintiff's Losartan were Hetero, Hetero Labs, Hetero USA, Camber, Torrent Private, Torrent Pharmaceuticals, Torrent Pharma, Macleods Pharmaceuticals Ltd., Macleods Pharma USA, Inc. and Walgreens, as defined below. This Losartan was contaminated with NDMA, NMBA, NDEA, or another nitrosamine. Plaintiff thus suffered cellular and genetic injury that creates and/or increases the risk that Plaintiff will develop cancer.

B. The Active Pharmaceutical Ingredient Manufacturer Defendants

16. For ease of reference, this Master Complaint generally organizes Defendants by the distribution level at which they principally operate. The following Defendants manufacture the active pharmaceutical ingredient ("API") for Defendants' LCDs, or are closely affiliated with an entity that does so. The inclusion of certain Defendants in this section does not mean they are not properly classifiable as another type of defendant, or vice versa (e.g., a Defendant listed in this subsection may also be a distributor; a Defendant listed in the distributor subsection may also be an API manufacturer).

17. The finished-dose manufacturer defendants' LCDs have unique labelers/distributors, as well as repackagers.

1. Hetero Labs, Ltd. Entities

18. Defendant Hetero Labs, Ltd. ("Hetero Labs") is a foreign corporation, with its principal place of business at 7-2-A2, Hetero Corporate, Industrial Estates, Sanath Nagar, Hyderabad – 500 018, Telangana, India. Hetero Labs on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this action, Hetero Labs has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic LCDs throughout the United States.

19. Defendant Hetero Drugs, Limited ("Hetero") is a foreign corporation, with its principal place of business at 7-2-A2, Hetero Corporate, Industrial Estates, Sanath Nagar, Hyderabad - 500 018, Telangana, India. "Hetero has a strong established global presence with 36 manufacturing facilities and a robust network of business partners and marketing offices strategically located across the world."[6] Hetero on its own and/or through its subsidiaries regularly conducts business in New Jersey and throughout the United States and its territories and possessions. Hetero Labs is the wholly-owned subsidiary of Hetero. At all times material to this action, Hetero has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic LCDs throughout the United States.

20. Defendant Hetero USA Inc. ("Hetero USA") is "the US representation of HETERO, a privately owned; researched based global pharmaceutical company."[7] Hetero USA is a Delaware corporation with its principal place of business located at 1035 Centennial Avenue, Piscataway, New Jersey 08854. Hetero USA is the wholly-owned subsidiary of Hetero. At all times material to this action, Hetero USA has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic LCDs throughout the United States.

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6 Hetero, GLOBAL FOOTPRINT, https://www.heteroworld.com/global-footprint.php.

7 Hetero USA, LINKEDIN, https://www.linkedin.com/company/hetero-usa-inc/about/.

21. Defendant Camber Pharmaceuticals, Inc. ("Camber") is a Delaware corporation, with its principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854. Camber is the wholly owned subsidiary of Hetero Drugs. At all times material to this action, Camber has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, misbranded, and/or unapproved LCDs throughout the United States.

22. Defendant Legacy Pharmaceutical Packaging, LLC is a Missouri limited liability company with its principal place of business at 13333 Lakefront Drive, Earth City, Missouri 63045.

23. Defendant Legacy Pharmaceutical Packaging, LLC purchased LCDs from Defendant Camber Pharmaceuticals and subsequently sold them to Defendant Wal-Mart for distribution.

24. Defendant Legacy Pharmaceutical Packaging, LLC also purchased and sold product sourced from Torrent, which contained API sourced from Hetero.

25. At all times material to this action, Legacy Pharmaceutical Packaging, LLC has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

26. Defendant H. J. Harkins Company, Inc., dba Pharma Pac is a California corporation, with its principal place of business at 1400 West Grand Avenue, Suite F, Grover Beach, CA, 93433.

27. Defendant H.J. Harkins Co. Inc. is a repackager for LCDs manufactured by Camber, which contained API from Defendant Hetero Labs.

28. Collectively, Hetero Labs, Hetero, Hetero USA, Camber, Legacy, and Harkins will be referred to as the Hetero Defendants in this Complaint.

C. The Finished-Dose and Labeling Defendants[8]

29. Defendant Teva Pharmaceutical Industries Ltd. ("Teva") is a foreign company incorporated and headquartered in Petah Tikvah, Israel. Teva on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Teva has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic LCDs in the United States.

30. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation, with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is a wholly owned subsidiary of Teva. At all times material to this case, Teva USA has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic LCDs in the United States.

[8] The Hetero Defendants also qualify as finished dose Defendants, but the party allegations are listed above.

31. Teva USA manufactured LCDs with API manufactured by Defendant Hetero Labs.

32. Defendant Golden State Medical Supply, Inc. is a California corporation, with its principal place of business at 5187 Camino Ruiz, Camarillo, California 93012. Defendant Golden State Medical Supply, Inc. purchased LCDs from Defendant Teva Pharmaceuticals USA, Inc. At all times material to this action, Golden State Medical Supply, Inc. has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

33. Defendant Vivimed Life Sciences Pvt Ltd ("Vivimed") is a foreign corporation, with its principal place of business at Plot No. 101, 102, 107 & 108, SIDCO Pharmaceutical Complex, Alathur, Kanchipuram – 603 110, Tamilnadu, India. Defendant Vivimed purchased LCDs from Defendant Hetero Labs, Ltd. and subsequently sold them to Defendant Heritage Pharmaceuticals, Inc. At all times material to this action, Defendant Vivimed has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

34. Defendant Heritage Pharmaceuticals, Inc. d/b/a/ Avet Pharmaceuticals ("Heritage Pharmaceuticals") is a Delaware corporation, with its principal place of business at One Town Center Boulevard, East Brunswick, New Jersey 08816.

Defendant Heritage purchased LCDs from Defendant Vivimed. At all times material to this action, Defendant Heritage has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

35. Defendant Macleods Pharmaceuticals Ltd. is a foreign corporation, with its principal place of business at Atlanta Arcase, Marol Church Road, Andheri (east), Mumbai – 400059, India. Defendant Macleods Pharmaceuticals Ltd. purchased LCDs from Defendant Hetero and sold these LCDs through its subsidiary, Macleods Pharma USA, Inc. At all times material to this action, Defendant Macleods Pharmaceuticals Ltd. has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

36. Defendant Macleods Pharma USA, Inc. is a Delaware corporation, with its principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536. Defendant Macleods Pharma USA is a wholly owned subsidiary of Macleods Pharmaceuticals, Ltd. and sold LCDs manufactured by Macleods Pharmaceuticals, Ltd., containing API sourced from Hetero. At all times material to this action, Defendant Heritage has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

37. Defendant Torrent Private Limited ("Torrent") is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India, and a United States headquarters at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. Torrent on its own and/or through its subsidiaries regularly conducts business throughout the United States of America and its territories and possessions. At all times material to this case, Torrent has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded LCDs in the United States.

38. Defendant Torrent Pharmaceuticals, Ltd. ("Torrent Pharmaceuticals") is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India, and a United States headquarters at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. Over seventy percent of Torrent Pharmaceuticals is owned by Torrent. Torrent Pharmaceuticals on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Torrent Pharmaceuticals has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded LCDs in the United States.

39. Torrent Pharmaceuticals manufactured finished dose LCDs with API purchased from Hetero.

40. Defendant Torrent Pharma, Inc. ("Torrent Pharma") is a Delaware corporation with its principal place of business at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. It is a wholly-owned subsidiary of Torrent Pharmaceuticals. At all times material to this case, Torrent Pharma has been engaged in the manufacturing, sale, and distribution of contaminated LCDs in the United States. The LCDs sold and distributed by Torrent Pharma contained API sourced from Hetero.

41. Torrent, Torrent Pharmaceuticals, and Torrent Pharma are referred to collectively as the "Torrent Defendants" in this Complaint.

42. Defendant Major Pharmaceuticals, Inc. is a corporation, with its principal place of business at 17177 North Laurel Park, Suite 233, Livonia, MI 48152.

43. Defendant Major Pharmaceuticals, Inc. distributed LCDs supplied by Torrent, with API manufactured by Hetero.

44. Defendant AvKARE, Inc. is a Tennessee corporation, with its principal place of business at 615 N 1st Street, Pulaski, TN 38478-2403.

45. Defendant AvKARE, Inc. sold, repackaged, and/or relabeled LCDs purchased from Macleods Pharma USA, Inc. and Macleods Pharmaceuticals Ltd., which contained API sourced from Hetero. At all times material to this action,

Defendant Heritage has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

46. Defendant RemedyRepack, Inc. is a Pennsylvania corporation, with its principal place of business at 625 Kolter Drive, Suite 4, Indiana, PA 15701.

47. Defendant RemedyRepack is a repackager for LCDs manufactured by Torrent, with API coming from Hetero.

48. Defendant Preferred Pharmaceuticals, Inc. is a California corporation, with its principal place of business at 1250 North Lakeview Ave., Unit O, Anaheim CA 92807.

49. Preferred Pharmaceuticals, Inc. is a repackager for LCDs manufactured by Torrent, which contained API sourced from Hetero.

50. Defendant Legacy Pharmaceutical Packaging, LLC (mentioned above) also was a repackager for the Torrent Defendants with API sourced from the Hetero Defendants.

D. Retail Pharmacy Defendants

51. Retail pharmacies have supply arrangements with finished-dose manufacturers. They stand in direct contractual privity with consumers, insofar as retail pharmacies (be they brick-and-mortar or mail-order) are the entities that dispensed and received payments for the contaminated, adulterated, and/or

misbranded LCDs for which consumers paid and consumed. The following Defendants are collectively referred to as the "Pharmacy Defendants."

1. CVS Health

52. Defendant CVS Health Corporation ("CVS Health") is a national retail pharmacy chain incorporated in Delaware with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island.

53. As of March 31, 2019, Defendant CVS Health maintained approximately 9,900 retail pharmacy locations across the United States, making it one of the largest in the country. Defendant CVS Health also operates approximately 1,100 walk-in medical clinics and a large pharmacy benefits management service with approximately 94 million plan members.

54. According to its 2018 Annual Report, Defendant CVS Health's "Pharmacy Services" segment:

> provides a full range of pharmacy benefit management ("PBM") solutions, including plan design offerings and administration, formulary management, retail pharmacy network management services, mail order pharmacy, specialty pharmacy and infusion services, Medicare Part D services, clinical services, disease management services and medical spend management. The Pharmacy Services segment's clients are primarily employers, insurance companies, unions, government employee groups, health plans, Medicare Part D prescription drug plans ("PDPs"), Medicaid managed care plans, plans offered on public health insurance exchanges and private health insurance exchanges, other sponsors of health benefit plans and individuals throughout the United States.

55. CVS Health's Pharmacy Services segment generated U.S. sales of approximately $134.1 billion in 2018.

56. CVS Health's Retail/LTC segment is responsible for the sale of prescription drugs and general merchandise. The Retail/LTC segment generated approximately $84 billion in U.S. sales in 2018, with approximately 75% of that attributed to the sale of pharmaceuticals. During 2018 the Retail/LTC segment filled approximately 1.3 billion prescriptions on a 30-day equivalent basis. In December 2018, CVS's share of U.S. retail prescriptions accounted for 26% of the United States retail pharmacy market.

57. In or about 2015, CVS Health acquired all of Target Corporation's pharmacies. "CVS," as defined herein, includes any current or former Target pharmacy.

58. In 2014, CVS Health and wholesaler Cardinal Health, Inc. ("Cardinal") established a joint venture to source and supply generic pharmaceutical products through a generic pharmaceutical sourcing entity named Red Oak Sourcing, LLC ("Red Oak"), of which CVS Health and Cardinal each own fifty percent. Most or all of the losartan-containing drugs purchased by CVS Health were acquired through this joint venture with Cardinal.

59. Upon information and belief, Defendant CVS Health sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

2. Walgreens

60. Defendant Walgreen Co. is an Illinois corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015.

61. Upon information and belief, Defendant Walgreens Co. sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

62. Defendant Walgreens Boots Alliance, Inc. ("Walgreens") is a national retail pharmacy chain incorporated in the State of Delaware with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois.

63. Walgreen Co. and Walgreens Boots Alliance, Inc. are collectively referred to within this Complaint as "Walgreens."

64. Walgreens is one of the retail pharmacy chains in the United States, offering retail pharmacy services and locations in all 50 states including the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. As of August 31, 2018, Walgreens operated 9,560 retail pharmacies across the United States, with 78% of the U.S. population living within five miles of a store location. In addition, Walgreens recently purchased an additional 1,932 store locations from rival Rite Aid Corporation, further consolidating the industry. Walgreens' sales amounted to a staggering $98.4 billion in 2018, most of which are generated for prescription sales. Walgreens accounts for nearly 20% of the U.S. market for retail prescription drug sales.

65. Walgreens is one of the largest purchasers of pharmaceuticals in the world, and according to its Form 10-K for 2018, the wholesaler AmerisourceBergen "supplies and distributes a significant amount of generic and branded pharmaceutical products to the [Walgreens] pharmacies."

66. In or about 2017, Walgreens acquired control of Diplomat Pharmacy. "Walgreens," as defined herein, includes any current or former Diplomat pharmacy.

67. Defendant Walgreens sold a large portion of the contaminated, adulterated, and/or misbranded LCDs to U.S. consumers during the class period as defined below.

3. Express Scripts

68. Defendant Express Scripts, Inc. is a corporation, with its principal place of business at One Express Way, St. Louis, MO 63121.

69. Express Scripts, Inc. is a subsidiary of Express Scripts Holding Company.

70. Defendant Express Scripts, Inc. sold LCDs directly to Plaintiffs.

71. Express Scripts, Inc. was acquired by Cigna Corporation in 2018.

72. Upon information and belief, Defendant Express Scripts, Inc. sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

73. Defendant Express Scripts Holding Company is a corporation, with its principal place of business at One Express Way, St. Louis, MO 63121.

74. Express Scripts Holding Company is the parent corporation of Defendant Express Scripts, Inc.

75. Express Scripts was acquired by Cigna Corporation in 2018.

76. Upon information and belief, Defendant Express Scripts Holding Company, together with its corporate affiliates, sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

4. Cigna

77. Defendant Cigna Corporation is a corporation, with its principal place of business at 900 Cottage Grove Road, Bloomfield, CT 06002.

78. Defendant Cigna Corporation acquired Defendant Express Scripts, Inc. and its holding company, Express Scripts Holding Company in 2018.

79. Upon information and belief, Defendant Cigna Corporation, together with its corporate affiliates, sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

4. OptumRX

80. Defendant OptumRx is a Minnesota corporation with its principal place of business at 2300 Main Street, Irvine, CA 92614.

81. Defendant Optum, Inc. is a Minnesota corporation with its principal place of business at 11000 Optum Circle, Eden Prairie, MN 55344. Upon information and belief, Defendant Optum Rx is a wholly-owned subsidiary of Defendant Optum, Inc.

82. Defendants OptumRx and Optum, Inc. sold a large portion of the contaminated, adulterated, and/or misbranded LCDs to U.S. consumers during the class period as defined below.

83. Defendant UnitedHealth Group is a Minnesota corporation, with its principal place of business at 11000 Optum Circle, Eden Prairie, MN 55344.

84. Upon information and belief, Defendant Optum, Inc. is a wholly owned subsidiary of UnitedHealth Group.

85. Upon information and belief, Defendant UnitedHealth Group, together with its corporate affiliates, sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

4 United Health Group

86. Defendant United Health Group is a Minnesota corporation, with its principal place of business at 11000 Optum Circle, Eden Prairie, MN 55344.

87. Upon information and belief, Defendant Optum, Inc. is a wholly owned subsidiary of UnitedHealth Group.

88. Upon information and belief, Defendant United Health Group, together with its corporate affiliates, sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

5. Walmart

89. Defendant Walmart Stores, Inc. ("Wal-Mart") is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

90. According to Defendant Wal-Mart's 2018 Form 10-K, Wal-Mart maintains approximately 4,769 retail locations in all fifty states nationwide and the District of Columbia and Puerto Rico (including supercenters, discount stores, and neighborhood markets and other small format locations). Most or all of these locations have Wal-Mart health and wellness products and services, which includes prescription pharmaceutical services. There are another approximately 600 Sam's Club locations across the United States, all or nearly all offering prescription pharmaceutical services.

91. Defendant Wal-Mart (including Sam's Club) sold a large portion of the contaminated, adulterated, and/or misbranded LCDs to U.S. consumers across the country during the class period as defined below.

6. The Kroger Co.

92. Defendant The Kroger, Co., ("Kroger") is a corporation, with its principal place of business at 1014 Vine Street, Cincinnati, OH 45202.

93. Upon information and belief, Defendant The Kroger Co. sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

7. Rite Aid Corp.

94. Defendant Rite-Aid Corporation ("Rite-Aid") is a Delaware corporation with its principal place of business in Camp Hill, Pennsylvania.

95. Upon information and belief, Defendant Rite-Aid Corporation sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

8. Albertsons Companies, LLC

96. Defendant Albertsons Companies LLC ("Albertsons") is a limited liability company with its principal place of business in Boise, Idaho.

97. Upon information and belief, Defendant Albertsons Companies, LLC sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

9. Humana

98. Defendant Humana Pharmacy, Inc. is a corporation, with its principal place of business at 500 West Main Street, Louisville, KY 40202.

99. Defendant Humana Pharmacy, Inc. sold LCDs directly to Plaintiffs.

100. Upon information and belief, Defendant Humana Pharmacy, Inc. is a wholly owned subsidiary of Defendant Humana, Inc.

101. Upon information and belief, Defendant Humana, Inc. sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

102. Defendant Humana, Inc. is a corporation, with its principal place of business at 500 West Main Street, Louisville, KY 40202.

103. Upon information and belief, Defendant Humana, Inc. is the parent corporation of Humana Pharmacy, Inc.

104. Upon information and belief, Defendant Humana, Inc, together with its corporate affiliates, sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

E. Wholesaler Defendants

105. The generic drug supply chain from manufacturer to end consumer involves several groups of actors and links.

106. At the top of the supply chain are generic drug manufacturers (and whomever they contract with to manufacture components of pharmaceuticals including, for example, the active pharmaceutical ingredient manufacturer. Generic drug manufacturers may sell to other manufacturers or to so-called repackagers or labelers who sell a particular generic drug formulation.

107. Wholesalers in turn purchase bulk generic drug product from the generic manufacturers and/or labelers and repackager entities.

108. Wholesalers sell the generic drug products they acquire to retail pharmacies, who sell them to patients with prescriptions in need of fulfillment. The retail pharmacy market is also dominated by several major players.

109. The wholesaler market is extremely concentrated, with three entities holding about 92% of the wholesaler market: Cardinal Health, Inc.; McKesson Corporation; and AmerisourceBergen Corporation.

1. Cardinal Health

110. Defendant Cardinal Health, Inc. is an Ohio corporation with its principal place of business at 7000 Cardinal Place, Dublin, Ohio 43017. Cardinal has been engaged in the manufacturing, sale, and distribution of contaminated, adulterated, and/or misbranded generic LCDs in the United States, including in the State of New Jersey.

2. McKesson

111. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states. McKesson – either directly or through a subsidiary or affiliated – distributed contaminated, adulterated, and/or misbranded LCDs in the United States, including in the State of New Jersey.

3. AmerisourceBergen

112. Defendant AmerisourceBergen Corporation ("Amerisource") a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states. Amerisource – either directly or through a subsidiary or affiliated – distributed contaminated, adulterated, and/or misbranded LCDs in the United States, including in the State of New Jersey.

F. John Doe Defendants 1-50

113. The true names, affiliations, and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of John Does 1 through 50 are unknown to Plaintiffs at this time. Plaintiffs therefore sue these defendants using fictitious names. Each John Doe proximately caused damages to Plaintiffs as alleged below, and each John Doe is liable to Plaintiffs for the acts and omissions alleged below as well as the resulting damages. Plaintiffs will amend this Master Class Complaint to allege the true names and capacities of the John Does when evidence reveals their identities.

114. At all times relevant to this Master Class Complaint, each of the John Does was the agent, servant, employee, affiliate, and/or joint venturer of the other co-defendants and other John Does. Moreover, each Defendant and each John Doe

acted in the full course, scope, and authority of that agency, service, employment, and/or joint venture.

G. JURISDICTION AND VENUE

115. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendants, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.

116. This Court has personal jurisdiction over Defendants pursuant to 28 U.S.C. § 1407, and because Defendants have sufficient minimum contacts in New Jersey, and because Defendants have otherwise intentionally availed themselves of the markets within New Jersey through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

117. Venue is proper in this District on account of the MDL consolidation pursuant to 28 U.S.C. § 1407 and because Defendants reside in this District, 28 U.S.C. § 1391(b)(1); "a substantial part of the events or omissions giving rise to the claim occurred" in this District, 28 U.S.C. § 1391(b)(2); and Defendants are subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

III. FACTUAL ALLEGATIONS

A. Generic Drugs Must Be Chemically the Same as Branded Drug Equivalents

118. According to the FDA, "[a] generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that **a generic medicine works in the same way and provides the same clinical benefit as its brand-name version.** In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."[9]

119. While brand-name medications undergo a more rigorous review before being approved, generic manufacturers are permitted to submit an ANDA, which only requires a generic manufacturer to demonstrate that the generic medicine is the same as the brand-name version in the following ways:

a. The active ingredient(s) in the generic medicine is/are the same as in the brand-name drug/innovator drug.

b. The generic medicine has the same strength, use indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical).

[9] FDA, GENERIC DRUGS: QUESTIONS & ANSWERS, https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (emphasis in original).

c. The inactive ingredients of the generic medicine are acceptable.

d. The generic medicine is manufactured under the same strict standards as the brand-name medicine.

e. The container in which the medicine will be shipped and sold is appropriate, and the label is the same as the brand-name medicine's label.[10]

120. The drugs ingested by Plaintiffs were approved by the FDA, based upon Defendants' representations that they met the above criteria.

121. ANDA applications do not require drug manufacturers to repeat animal studies or clinical research on ingredients or dosage forms already approved for safety and effectiveness.[11]

122. Further, because generic drugs are supposed to be nearly identical to their brand-name counterparts, they are also supposed to have the same risks and benefits.[12]

B. Misbranded and Adulterated or Misbranded Drugs

123. The manufacture of any adulterated or misbranded drug is prohibited under federal law.[13]

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[10] FDA, GENERIC DRUG FACTS, https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm167991.htm.

[11] FDA, GENERIC DRUGS: QUESTIONS & ANSWERS, https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.

[12] *Id.*

[13] 21 U.S.C. § 331(g).

124. The introduction into commerce of any misbranded or adulterated or misbranded drug is similarly prohibited.[14]

125. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.[15]

126. Among the ways a drug may be adulterated and/or misbranded are:

a. "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;"[16]

b. "if … the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice…as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;"[17]

c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and … its quality or purity falls below, the standard set forth in such compendium. …"[18]

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14 21 U.S.C. § 331(a).
15 21 U.S.C. § 331(c).
16 21 U.S.C. § 351(a)(2)(A).
17 21 U.S.C. § 351(a)(2)(B).
18 21 U.S.C. § 351(b).

d. "If … any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[19]

127. A drug is misbranded:

a. "If its labeling is false or misleading in any particular."[20]

b. "If any word, statement, or other information required…to appear on the label or labeling is not prominently placed thereon…in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[21]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient…"[22]

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. …"[23]

19 21 U.S.C. § 351(d).
20 21 U.S.C. § 352(a)(1).
21 21 U.S.C. § 352(c).
22 21 U.S.C. § 352(e)(1)(A)(ii)
23 21 U.S.C. § 352(f).

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein."[24]

f. "if it is an imitation of another drug;"[25]

g. "if it is offered for sale under the name of another drug."[26]

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[27]

i. If the drug is advertised incorrectly in any manner;[28] or

j. If the drug's "packaging or labeling is in violation of an applicable regulation…"[29]

128. As articulated in this Complaint, Defendants' unapproved drug was adulterated and/or misbranded as a result of contamination with NDMA, NMBA and NDEA, which was not approved, and was not disclosed.

129. The medication at issue in this action is a drug that Defendants manufactured, marketed and sold under the name "Losartan".

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24 21 U.S.C. § 352(g).
25 21 U.S.C. § 352(i)(2).
26 21 U.S.C. § 352(i)(3).
27 21 U.S.C. § 352(j).
28 21 U.S.C. § 352(n).
29 21 U.S.C. § 352(p).

130. Losartan is a generic version of the brand-name medication, Cozaar, and Losartan with hydrochlorothiazide (HCTZ) is a generic version of the brand-name medication, Hyzaar.

131. Losartan is used to treat high blood pressure and heart failure, and to improve a patient's chance of living longer after a heart attack.

132. Losartan is classified as an ARB that is selective for the type II angiotensin receptor. It works by relaxing blood vessels so that blood can flow more easily thereby lowering blood pressure.

133. Losartan potassium can be sold by itself or as a single pill which combines Losartan with HCTZ.

134. The drug binds to angiotensin type II receptors (ATI) working as an antagonist.

135. The patents for Cozaar and Hyzaar expired in August 2009.

136. Shortly after the patents for Cozaar and Hyzaar expired, the FDA began to approve generic versions of the drugs.

C. The Drugs Ingested by Plaintiffs Were Not Losartan, But New, Unapproved LCDs

137. The FDA's website provides the definition for a drug:

> The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA regulations define the term drug, in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to

> affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated by FDA as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients.[30]

138. 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."

139. NDMA, NMBA and NDEA cause cellular and genetic injury triggering genetic mutations in humans that can ultimately develop into cancer. These injuries affect the structure of the human body, and thus, NDMA, NMBA and NDEA are, by definition, active ingredients in a drug.

140. FDA further requires that whenever a new active ingredient is added to a drug, the drug becomes an entirely new drug, necessitating a submission of a New

[30] FDA, HUMAN DRUGS, https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug.

Drug Application by the manufacturer. Absent such an application, followed by a review and approval by the FDA, this new drug remains a distinct, unapproved product.[31]

141. This new and unapproved drug with additional active ingredients (such as nitrosamines in the subject LCDs) cannot be required to have the same label as the brand-name drug, as the two products are no longer the same.

142. At the very least and alternatively, drugs contaminated with different and dangerous ingredients than their brand-name counterparts are adulterated or misbranded under federal law, and the sale or introduction into commerce of adulterated or misbranded drugs is illegal.[32]

143. Because the LCDs ingested by Plaintiffs were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs. Further, if such an assessment were performed, the drugs would not have been approved because they were contaminated with NDMA, NMBA and/or NDEA.

144. The inclusion of additional active ingredients (NDMA, NMBA and NDEA), and potentially other deviations from Defendants' ANDA approvals

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31 *See* 21 C.F.R. § 310.3(h).

32 *See generally* Department of Justice, *Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA* (May 13, 2013), https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false.

rendered Defendants' LCDs unapproved, adulterated, misbranded drugs that are distinct from the FDA-approved generic Losartan. Plaintiffs reference federal law in this Complaint not in any attempt to enforce it, but to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

D. Defendants Made False Statements in the Labeling of its LCDs

145. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[33] and conform to requirements governing the appearance of the label.[34]

146. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[35] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

147. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did

33 21 C.F.R. § 201.5.
34 21 C.F.R. § 801.15.
35 *Id.*; 65 Fed. Reg. 14286 (March 16, 2000).

not, and we cannot, exclude from the definition printed matter which constitutes advertising."[36]

148. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.

149. In addition, by referring to their drugs as "losartan" Defendants were making false statements regarding their LCDs.

150. Because NDMA, NMBA and/or NDEA were not disclosed by Defendants as ingredients in the LCDs ingested by Plaintiffs, the Defendants failed to warn consumers and physicians of the true ingredients, and the subject drugs were misbranded.

151. It is unlawful to introduce a misbranded drug into interstate commerce.[37] Thus, the LCDs ingested by individual Plaintiffs were unlawfully distributed and sold.

E. The Generic Drug Supply Chain in the United States

152. The generic drug supply chain from manufacturer to end consumer involves several groups of actors and links.

153. At the top of the supply chain are generic drug manufacturers (and whomever they contract with to manufacture components of pharmaceuticals

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36 *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).

37 21 U.S.C. § 331(a).

including, for example, the active pharmaceutical ingredient manufacturer ("API")). Generic drug manufacturers may sell to other manufacturers or to so-called repackagers or labelers who sell a particular generic drug formulation.

154. Wholesalers in turn purchase bulk generic drug product from the generic manufacturers and/or labelers and repackager entities. The wholesaler market is extremely concentrated, with three entities holding about 92% of the wholesaler market: Cardinal Health, Inc.; McKesson Corporation; and AmerisourceBergen Corporation.

155. Wholesalers sell the generic drug products they acquire to retail pharmacies, who sell them to patients with prescriptions in need of fulfillment. The retail pharmacy market is also dominated by several major players.

F. Background on Current Good Manufacturing Practices ("cGMPs")

156. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

157. 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and

strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

158. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

159. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

160. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j).

Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors' operations.

161. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract: There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

162. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

163. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products

conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

164. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

G. The Generic Drug Approval Framework

165. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

166. The stated purpose of Hatch-Waxman is to strike a balance between rewarding genuine innovation and drug discovery by affording longer periods of brand drug marketing exclusivity while at the same time encouraging generic patent challenges and streamlining generic drug competition so that consumers gain the benefit of generic drugs at lower prices as quickly as possible.

167. Brand drug companies submitting a New Drug Application ("NDA") are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

168. By contrast, generic drug companies submit an ANDA. Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

H. ANDA Applications Must Demonstrate Bioequivalence

169. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two drug products is evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

170. As part of its showing of bioequivalence pursuant to 21 C.F.R. § 314.50(d), the ANDA must also contain specific information establishing the drug's stability, including:

> a full description of the drug's substance, including its physical and chemical characteristics and stability; and the specifications necessary to ensure the identify strength, quality and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability.

171. Generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C).

172. A generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

I. ANDA Applications Must Provide Information About the Manufacturing Plants and Processes

173. The ANDA application must also include information about the manufacturing facilities of the product, including the name and full address of the facilities, contact information for an agent of the facilities, and the function and responsibility of the facilities.

174. The ANDA application must include a description of the manufacturing process and facility and the manufacturing process flow chart showing that there are adequate controls to ensure the reliability of the process.

175. Further, the ANDA application must contain information pertaining to the manufacturing facility's validation process, which ensures that the manufacturing process produces a dosage that meets product specifications.

J. ANDA Applications Must Comply with cGMPs

176. Additionally, ANDA applications must include certain representations pertaining to compliance with cGMPs.

177. The ANDA application is required to contain cGMP certifications for both the ANDA applicant itself, and also the drug product manufacturer (if they are different entities).

K. ANDA Approval is Contingent upon Continuing Compliance with ANDA Representations of Sameness

178. Upon granting final approval for a generic drug, the FDA will typically state that the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD[38] branded drug. Pharmacists, physicians, and patients can expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the same labeling as the RLD delivered to consumers

[38] The FDA's Drug Glossary defines an RLD as follows: "A Reference Listed Drug (RLD) is an approved drug product to which new generic versions are compared to show that they are bioequivalent. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New Drug Application (ANDA). By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand- name counterpart."

in each prescription of its generic products. Further, by simply marketing generic drugs pursuant to the brand-name drug's label under the generic name, generic manufacturers warrant that the generic drug is therapeutically equivalent to the brand-name drug.

179. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new and unapproved drug.

180. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, the generic manufacturer may no longer rely on the brand-name drug's labeling.

181. According to the FDA, there are at least twenty-one ANDAs approved for generic Cozaar and sixteen for generic Hyzaar.

L. Starting as Early as 2007, Defendants Were Actively Violating cGMPs in Their Foreign Manufacturing Facilities

182. For some time, Defendants have known that generic drugs manufactured overseas, particularly in China and India, were found or suspected to be less safe and effective than their branded equivalents or domestically-made generics due to their grossly inadequate manufacturing processes, procedures and compliance with cGMPs.

183. Defendants' foreign manufacturing operations were no exception to this.

1. Hetero's Inadequate Manufacturing Processes Results in Adulterated, Misbranded Drugs

184. Defendant Hetero maintains six API manufacturing facilities in India, which have been approved by the FDA to produce active ingredients for drugs being sold and marketed in the United States.

185. Hetero has a history of deviations from FDA's cGMP standards.

186. In December of 2016, during an inspection of an oral solid dose drug product manufacturing facility, the FDA observed, through closed circuit TV surveillance, that Hetero Quality Assurance technicians and "other individuals" were recorded destroying and altering records pertaining to commercial batch manufacturing immediately before the FDA's onsite regulatory inspection. According to a scathing letter, the FDA noted that the following occurred:

a. Hetero employees brought in a document shredder into the "DOCUMENTS STORAGE AREA" four days prior to the FDA inspection;

b. The FDA observed extensive shredding of what appeared to be "controlled documents" as well as "extensive signing of documents" by Quality Assurance technicians. The FDA noted that the documents were of a color consistent with batch packaging records and batch manufacturing records. Hetero failed to maintain documentation of what had been shredded;

c. One day prior to the FDA inspection a Hetero contract employee in the Quality Assurance division removed documents from the shredder and placed them in his pocket; and

d. At 1:13 am the morning the FDA inspectors were set to arrive at Hetero for their regulatory inspections, individuals were seen shredding documents.

187. In addition to the documented destruction of these manufacturing records, the FDA further observed that production and control records were not prepared for each batch of drug product produced and did not include complete information relating to the production and control of each batch.

188. Additionally, data derived from Hetero's programmable logic controller for compression machines was inconsistent with batch records and validation reports that were submitted to the FDA in support of applications to manufacture and market drugs in the United States.

189. Hetero also failed to include findings of any investigations and follow-up that occurred as a result of investigations into complaints about their drugs.

190. During the December 2016 inspection, equipment at Hetero was found to have not been cleaned and maintained at appropriate intervals to "prevent contamination that would alter the safety, identity, strength, quality and purity" of Hetero drug products.

191. During the December 2016 visit, FDA inspectors found that "accuracy, sensitivity and reproducibility of test methods" were not established and documented.

192. In an August 15, 2017, warning letter, the FDA strongly recommended that Hetero engage "a consultant, qualified as set forth in 21 CFR 211.34" to assist Hetero Labs in meeting cGMP requirements, but that, ultimately, "executive management remains responsible for fully resolving all deficiencies and ensuring ongoing cGMP compliance."

193. In February of 2018, FDA investigators discovered other manufacturing flaws at an API Manufacturing facility.

194. For example, the FDA found that there was a "failure" by Hetero to "thoroughly review any unexplained discrepancy and failure of a batch or any of its components to meet any of its specifications," whether or not the batch had been already distributed.

195. The FDA investigators further found during that February 2018 inspection that Hetero employees who were engaged in the processing, holding and testing of a drug product lacked the training and experience required to perform their assigned functions. Indeed, in a walk-through with FDA investigators, several quality-control personnel could not explain their assigned functions and processes after "repeated opportunities" to do so.

196. Additionally, FDA investigators concluded that there was "no assurance" that equipment used in API production was being maintained and/or kept under proper conditions for manufacturing operations "to prevent the contamination of the products handled and/or processed in the equipment." Likewise, equipment at Hetero was found to have not been cleaned and maintained at appropriate intervals to "prevent contamination that would alter the safety, identity, strength, quality and purity" of Hetero's drug products.

197. After recalls of Hetero's valsartan containing drugs, FDA Laboratory Analysis testing would later reveal that valsartan 320mg API manufactured by Hetero contained NDMA levels in excess of the FDA's interim limits[39] of 96 ng/day or 0.3 ppm.[40]

198. Subsequently, five different finished dose manufacturers issues recalls of LCDs containing API manufactured from Hetero Labs. These recall notices stated that the LCDs were being recalled because they contained "unacceptable" levels of nitrosamines which exceeded the FDA's set interim limits for NDMA, NDEA, and NMBA.[41]

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[39] To be clear, Hetero's valsartan products should not contain any NDMA.

[40] FDA, LABORATORY ANALYSIS OF VALSARTAN PRODUCTS, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products; *see also* FDA, FDA UPDATES AND PRESS ANNOUNCEMENTS ON ANGIOTENSIN II RECEPTOR BLOCKER (ARB) RECALLS (VALSARTAN, LOSARTAN, AND IRBESARTAN), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

[41] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-

M. Warranties Common to All Manufacturer Defendants

199. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book.[42] The Orange Book is a public document; Defendants sought and received the inclusion of their products in the Orange Book upon approval of their ANDAs. In securing FDA approval to market generic LCDs in the United States as an Orange Book-listed drug, Defendants were required to demonstrate that their generic LCDs were bioequivalent to their RLDs.

200. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book, therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.

201. Each Defendant's LCD is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved LCD label, Defendants, as generic manufacturers, made representations and express or implied warranties to consumers like Plaintiffs of the "sameness" of their products to the LCD's RLD, and that their products were consistent with the safety, quality, purity, identity, and strength

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[42] FDA, Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) Short Description, *at* https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm.

characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded or misbranded.

202. By introducing their respective LCDs into the United States market as a therapeutic equivalent to their RLDs and with the FDA-approved label that is the same as that of the RLDs, Defendants represent and warrant to physicians and patients like Plaintiffs that their LCDs are in fact the same as and are therapeutically interchangeable with their RLDs.

203. In addition, each Defendant affirmatively misrepresented and warranted to physicians and patients like Plaintiffs through their websites, brochures, and other marketing or informational materials that their LCDs complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

204. The presence of nitrosamines in Defendants' LCDs: (1) renders Defendants' LCDs non-bioequivalent (*i.e.*, not the same) to their RLDs and thus non-therapeutically interchangeable with them, thus breaching Defendants' express warranties of sameness; (2) was the result of gross deviations from cGMPs rendering Defendants' LCDs non-therapeutically equivalent to their RLDs, thus breaching Defendants' express warranties of sameness; and (3) results in Defendants' LCDs containing an ingredient that is not also contained in their RLDs, also breaching Defendants' express warranty of sameness (and express warranty that the products

contained the ingredients listed on each Defendant's FDA-approved label). Each Defendant willfully, recklessly, or negligently failed to ensure their LCDs' labels and other advertising or marketing statements accurately conveyed information about their products.

205. At all relevant times, Defendants have also impliedly warranted that their LCDs were merchantable and fit for their ordinary purposes.

206. Naturally, due to its status as a probable human carcinogen as listed by both the IARC and the U.S. EPA, NDMA, NDEA, NMBA, and other nitrosamines are not FDA-approved ingredients in LCDs. The presence of NDMA, NDEA, NMBA and other similar nitrosamines or impurities in Defendants' LCDs means that Defendants violated implied warranties to Plaintiffs and their physicians. The presence of NDMA, NDEA, or NMBA in Defendants' LCDs results in Defendants' LCDs being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of their RLDs), breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

207. For these and other reasons, Defendants' LCDs are therefore adulterated, misbranded, and/or unapproved, and it was illegal for Defendants to have introduced such LCDs in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

208. Reasonable alternative designs to these contaminated LCDs were available, and Defendants should and could have manufactured actual generic losartan. This is especially so given that alternative, actual LCDs or competing medications with the same approved indications were available from other manufacturers.

209. Moreover, every consumer who purchased and ingested a contaminated LCD has been exposed to a nitrosamine, a carcinogenic agent with mutagenic properties that operates at the cellular and sub-cellular levels, that caused cellular and genetic injury creating and/or increasing the risk that Plaintiffs will develop cancer.

N. Hetero Defendants' Warranties

210. In touting itself, Hetero claims that it has:

> "over 36 advanced manufacturing facilities strategically located across the world – including India, USA, China, Russia, Egypt, Mexico and Indonesia. Approved by stringent global regulatory authorities, Hetero facilities have integrated quality systems and processes to ensure adherence to cGMP (current Good Manufacturing practices). They are also vertically integrated and can be utilised for large-scale production of APIs, formulations in various dosage forms rapidly. We make continuous investments in upgradation of manufacturing facilities with special emphasis on deploying advanced machinery and adopting latest technologies to comply with 21 CFR. Besides enabling us consistently produce high quality medicines at an affordable cost, it also helps us in passing through regulatory audits with relative ease. It is these

> advantages that make us the partner of choice for major global pharmaceutical companies.[43]

211. Indeed, Hetero further describes itself as:

> "a research-driven pharmaceutical company, is committed to the development, manufacturing and marketing of active pharmaceutical ingredients (APIs), intermediates and finished dosages. Today, Hetero is recognized as a world leader in process chemistry, API manufacturing, formulation development, manufacturing and commercialization. Hetero has around 18 state-of-the-art manufacturing facilities, which are cGMP compliant and have been approved by various Ministries of Health and regulatory authorities like US FDA, WHO, MCC - South Africa, MHRA-UK, TGA – Australia, PMDA – Japan, KFDA (Korea) among others. The company has a rich manufacturing product portfolio of over 200 products across a wide range of therapeutic categories. Hetero has a strong global presence in over 120 countries and has been offering API's and generic formulations to partners across the globe. . . . . Hetero, a privately-owned company, is recognized as one of the top 10 companies in the Indian pharmaceutical industry with an annual turnover of US$ 1.2 billion. With a dedication and support of its 15,000 employees, Hetero continues its commitment to manufacture high-quality drugs and save millions of lives across the world."[44]

212. Specifically with respect to its manufacturing of API, Hetero purports to be:

> "proficient in achieving regulatory approvals worldwide of both APIs and formulations. With an integrated quality system to ensure adherence to cGMP practices, Hetero is committed to quality and its manufacturing facilities are

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43 Hetero, Manufacturing Capabilities, https://www.heteroworld.com/manufacturing.php.

44 Camber, Our Parent Company: Hetero, http://camberpharma.com/about-us/hetero.

> approved by global regulatory agencies. In addition, Hetero continues to invest in its state-of-the-art manufacturing facilities and capabilities to ensure that it is able to provide the highest level of quality standards in the pharmaceutical industry."[45]

213. Hetero likewise goes to great lengths in describing its products as the same as the brand-name drug. It states that its generic drugs are:

> "copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Health care professionals and consumers can be assured that FDA approved generic drug products have met the same rigid standards as the innovator drug. All generic drugs approved by FDA have the same high quality, strength, purity and stability as brand-name drugs. And, the generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs. . . . . Generic drugs look different because certain inactive ingredients, such as colors and flavorings, may be different. These ingredients do not affect the performance, safety or effectiveness of the generic drug. They look different because trademark laws in the U.S. do not allow a generic drug to look exactly like other drugs already on the market. . . . . To find out if there is a generic equivalent for your brand-name drug, visit FDA.gov to view a catalog of FDA-approved drug products, as well as drug labeling. Since there is a lag time after generic products are approved and they appear in the "Orange Book", you should also consult the most recent monthly approvals for "First Generics" at FDA.gov.[46]

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45 Camber, Global Resources, http://camberpharma.com/global-resources.

46 Camber, About Generics, http://camberpharma.com/generics.

214. Camber compares its losartan to Avapro on its website's product catalog.[47]

O. Torrent Defendants' Warranties

215. Torrent Pharmaceuticals' website states that they, "strongly believe in providing quality medicines at affordable price to the patients. In this quest, primarily, we have inclined ourselves towards safeguarding both the qualitative and quantitative aspects with the help of our robust manufacturing technologies and manufacturing facilities."[48]

P. Vivimed Labs' Warranties

216. On its website, Vivimed touts that "Our chemistry touches lives. … Vivimed provides high performance products of quality and value to improve the lives of our clients' consumers."

Q. Macleods Defendants' Warranties

217. On its website, Macleods states, "Macleods has enjoyed rapid growth in the recent years, growing at an average growth rate of over 22% for the past 5 years.[49]

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47 Camber, Product, https://camberpharma.com/products?s=losartan.

48 Torrent Pharmaceuticals, Manufacturing, http://www.torrentpharma.com/Index.php/site/info/manufacturing.

49 https://www.macleodspharma.com/.

218. The website further states, "Macleods with its experience spanning more than two decades has emerged as a force to reckon with in the global pharmaceutical market ….With expertise in range of formulations ranging from tablets to sterile dosage form and from inhalation to novel drug delivery system, Macleods is currently ranked 10th (on mat basis source IMS) in Indian Pharmaceutical Industry and is recognized as one of the fastest growing pharmaceutical company in India. Pioneering efforts of Macleods in providing medications for both chronic and acute therapy, with world- class state-of-the-art manufacturing facilities approved by various regulatory authorities of many countries and well equipped R&D, analytical and bioequivalence center audited by various regulatory authorities makes Macleods truly a global pharmaceutical company."

R. Teva Defendants' Warranties

219. Teva has a "Generics FAQs" on its website.[50] In response to the question "Are generic drugs safe?" Teva states the following:

> A generic drug is bioequivalent to the original innovative drug and meets the same quality standards. The active ingredient, the content, the dosage form and the usage of a generic drug are similar to those of an innovative drug. Generic drugs are essentially the same as the original drug, but are offered at a lower price.

[50] Teva, PRODUCTS, http://www.tevapharm.com/our_products/generic_qa/.

220. In response to the question "How do you ensure generic drug safety, having tried it in only a limited number of patients?" Teva states the following:

> The generic product's active pharmaceutical ingredient (API) is identical to that of the innovative drug, its purity profile is similar and it is found to be bioequivalent; therefore its safety and efficacy are also comparable.

221. Similarly, under the webpage titled "Uncompromising Quality," Teva states that it knows that its products affect patient health. Teva further states that it "guarantee[s] the quality of our products" through Teva's "impeccable adherence to … [cGMPs][.]"

222. Teva's website states that "Our state-of-the-art manufacturing facilities feature the most advanced testing equipment to guarantee the quality of our products. Equipment is tested and certified, and every manufacturing process is validated. All supplier procedures are strictly supervised to ensure that only the highest grade materials are used in our products."[51]

223. According to Teva, "[o]ur manufacturing network is continuously optimized so that our customers can have full confidence in our supply chain. This is enabled by high-volume, technologically-advanced distribution facilities. These facilities allow us to deliver new products swiftly and reliably. We continually review our capabilities and capacity. This ensures that we can consistently deliver

[51] Teva, COMPANY PROFILE: UNCOMPROMISING QUALITY, https://www.tevapharm.com/about/profile/quality_assurance/.

best-in-class products. Our customers know that their end-consumers are receiving high-quality healthcare and wellness pharmaceuticals."[52]

224. Teva USA's website states, "Teva's commitment to quality is uncompromising and we manufacture according to the highest quality and compliance standards. This focus is evident at every stage of the development and production of our medicines. All of our manufacturing processes are validated and products are tested and certified, using state-of-the-art testing equipment throughout the manufacturing process designed to ensure adherence to the highest quality and compliance standards."[53]

225. Teva USA's Code of Conduct affirms, "To ensure we are in compliance and working in accordance with sound quality principles in our research laboratories, in our clinical trials, and in our manufacturing plants and distribution centers, we adhere to the systems and internal controls for 'Good Operating Practices,' or 'GxP,' including Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP) Good Pharmacovigilance Practices (GVP) and Good Distribution Practices (GDP)."[54]

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52 *Id.*

53 Teva USA, ABOUT TEVA: QUALITY YOU CAN TRUST, https://www.tevausa.com/About-Teva/article-pages/quality/.

54 Teva USA, TEVA CODE OF CONDUCT, https://www.tevausa.com/About-Teva/article-pages/Code-of-Conduct/.

S. Warranties Common to All Retail Pharmacy Defendants

226. Retail pharmacies are where consumers purchase and fill prescriptions for pharmaceuticals. As a result, retail pharmacies and consumers have direct privity of contract. With each sale of prescription drugs, retail pharmacies impliedly warrant to consumers that the prescription drugs being sold to them are merchantable and/or fit for its ordinary uses.

227. By selling pharmaceutical prescription drugs in the stream of commerce, each retail pharmacy defendant warrants that the generic drugs for which they receive payments are the same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics. More generally, retail pharmacy defendants warrant that prescription drugs they sell are of a standard quality.

228. Each Retail Pharmacy Defendants also supplied package inserts to Plaintiffs, which warranted that the drugs Plaintiffs received contained only the active ingredients on the label.

229. Further, each retail pharmacy defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

T. Wholesale Distributor Defendants' Warranties

230. Each distributor defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

231. Each Wholesale Distributor Defendants sold generic drugs as bioequivalents to the Brand Name drug.

U. Repackager and Relabeler Defendants' Warranties

232. By selling drugs in the stream of commerce, each repackager and relabeler defendant warrants that the generic drugs they sell are the same as existing brand-named drugs in active ingredient, dosage form, safety, strength, routes of administration, quality, and performance characteristics.

233. Further, each repackager and relabeler defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

V. The Contamination of Defendants' Losartan

1. The Nitrosamine Contaminant NDMA

234. N-nitrosodimethylamine, commonly known as NDMA, is an odorless, yellow liquid.[55]

[55] U.S. Public Health Service, *Toxicological Profile For N-Nitrosodimethylamine* (Dec 1989), https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

235. According to the U.S. Environmental Protection Agency ("EPA"), "NDMA is a semi-volatile chemical that forms in both industrial and natural processes."[56]

236. NDMA can be unintentionally produced in and released from industrial sources through chemical reactions involving other chemicals called alkylamines.

237. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[57]

238. The US Department of Health and Human Services (DHHS) similarly states that NDMA is reasonably anticipated to be a human carcinogen.[58] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[59]

239. Exposure to NDMA can occur through ingestion of food, water, or medication containing nitrosamines.[60]

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56 EPA, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17508.pdf.

57 *Id.*

58 *Id.*

59 *Id.*

60 *Id.*

240. Exposure to high levels of NDMA has been linked to liver damage in humans.[61]

241. According to the Agency for Toxic Substances and Disease Registry, "NDMA is very harmful to the liver of humans and animals. People who were intentionally poisoned on one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding."[62]

242. Other studies showed an increase in other types of cancers, including but not limited to stomach, colorectal, intestinal, kidney, liver, and other digestive tract cancers.

243. On July 27, 2018, the FDA put out a press release, explaining the reason for its concern regarding the presence of NDMA found in valsartan containing drugs. In that statement, the FDA provided, in relevant part:

> NDMA has been found to increase the occurrence of cancer in animal studies…Consuming up to 96 nanograms NDMA/day is considered reasonably safe for human ingestion.

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61 *Id.*

62 U.S. Public Health Service, *Toxicological Profile For N-Nitrosodimethylamine* (Dec 1989) , https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

244. The Environmental Protection Agency classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."[63]

245. The World Health Organization's ("WHO") International Agency for Research on Cancer ("IARC") classifies NDMA as one of sixty-six agents that are "probably carcinogenic to humans" (Classification 2A).

246. Anecdotally, NDMA has also been used in intentional poisonings.[64]

2. The Nitrosamine Contaminant NDEA

247. N-Nitrosodiethylamine, often referred to as NDEA, is a yellow, oily liquid that is soluble in water.[65]

248. Like NDMA, NDEA is also classified by DHHS and EPA as a probable human carcinogen and a known animal carcinogen.[66]

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[63] EPA, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17508.pdf.

[64] *See Chase Purdy, A common blood-pressure medicine is being recalled because of a toxic ingredient*, QUARTZ (July 18, 2018), https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/.

[65] EPA, *Integrated Risk Information System: N-Nitrosodimethylamine*, https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.

[66] Canada Department of Health, *Information Update - Mylan-Valsartan medications voluntarily recalled as a precaution due to an impurity* (Nov. 29, 2018) , https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/68448a-eng.php; see *also* FDA, *FDA provides update on its ongoing investigation into valsartan products; and reports on the finding of an additional impurity identified in one firm's already recalled products* (Sept. 13, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620499.htm.

249. According to the U.S. Environmental Protection Agency, even short-term exposure to NDEA can damage the liver in humans. Animal studies also demonstrate that chronic ingestion of NDEA can cause liver tumors and other types of tumors as well, including in the kidneys.

250. Hematological effects were also reported in animal studies.[67]

251. Tests conducted on rats, mice, and hamsters demonstrated that NDEA has high-to-extreme toxicity from oral exposure.[68]

252. The New Jersey Department of Health notes that NDEA "should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION."[69]

253. The New Jersey Department of Health also states that "[t]here may be no safe level of exposure to a carcinogen, so all contact should be reduced to the lowest possible level."[70]

254. The New Jersey Department of Health notes that NDEA is classified as a probable human carcinogen, as it has been shown to cause liver and gastrointestinal tract cancer, among others.[71]

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67 EPA, *Integrated Risk Information System: N-Nitrosodimethylamine*, https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.

68 *Id.*

69 New Jersey Department of Health, *Right to Know Hazardous Substance Fact Sheet: N-Nitrosodiethylamine* (July 2008), https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf (emphasis in original).

70 *Id.*

71 *Id.*

255. The IARC of WHO classifies NDEA as one of sixty-six agents that are "probably carcinogenic to humans" (Classification 2A).

3. The Nitrosamine Contaminant NMBA

256. NMBA is another nitrosamine that has been identified in sartan medications by the FDA.[72]

257. Due to its structural similarities to NDMA and NDEA, NMBA is considered by international regulators such as the World health Organization to have a similar toxicological profile to NDMA and NDEA.[73]

258. When NMBA was first discussed in an FDA press release, FDA noted, "We are deeply concerned about the presence of a third nitrosamine impurity in certain ARB medications, but it's important to underscore that, based on the FDA's initial evaluation, the increased risk of cancer to patients with NMBA exposure appears to be the same for NDMA exposure but less than the risk from NDEA exposure. That said, any presence of such impurities in drug products is not acceptable.[74]

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[72] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan

[73] https://www.who.int/medicines/publications/drugalerts/InformationNote_Nitrosamine-impurities/en/

[74] https://www.fda.gov/news-events/press-announcements/fda-provides-update-its-ongoing-investigation-arb-drug-products-reports-finding-new-nitrosamine

259. Thus, the FDA set interim consumption limits of NMBA at 96 nanograms per day, which is the same interim level set for daily consumption of NDMA.[75]

260. Like NDMA and NDEA, NMBA has been a chemical of choice used in animal studies to induce cancer in animal study subjects, because it is known to induce cancer.[76]

261. Testing and evaluation is ongoing of LCDs manufactured, distributed, or sold by Defendants. Besides these nitrosamines, ongoing investigation suggests other impurities, such as NMBA, may also exist in the LCDs at issue.

4. Formation of Nitrosamines in The Subject Drugs

262. These nitrosamines are considered genotoxic compounds, as they all contain nitroso groups, which are gene-mutating groups.[77]

263. N-nitrosamines are formed at the tetrazole ring present in ARB medications, including valsartan, losartan, and irbesartan. The tetrazole ring is visually depicted in the following diagram[78]:

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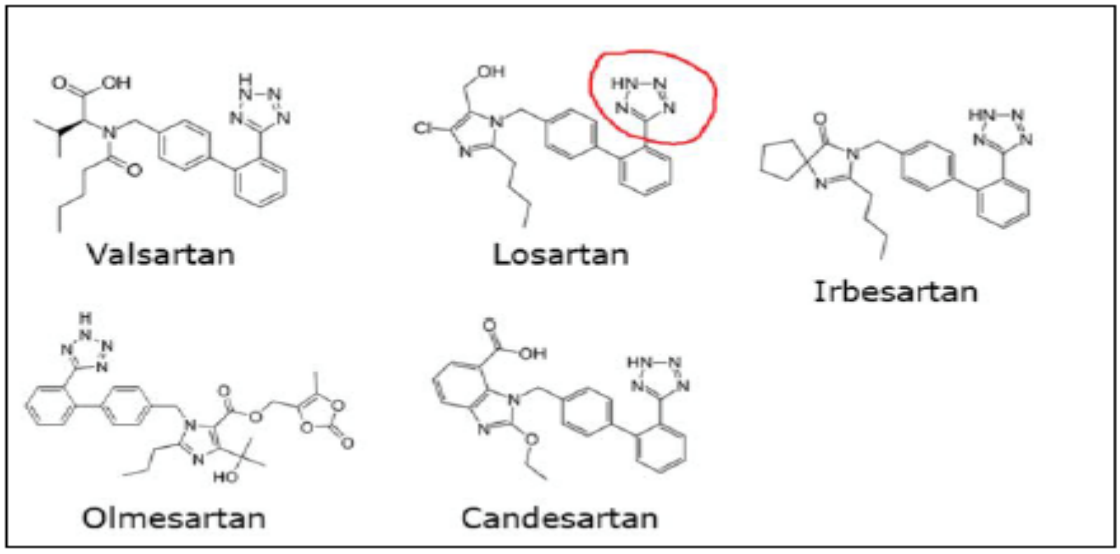
[75] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan

[76] https://pubmed.ncbi.nlm.nih.gov/3180095/

[77] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001

[78] Committee for Medicinal Products for Human Use, Assessment Report Article 31 Angiotensin-II-Receptor Antagonists (sartans) Containing a Tetrazole Group, at 3-4 (European Medicines Agency 2019).



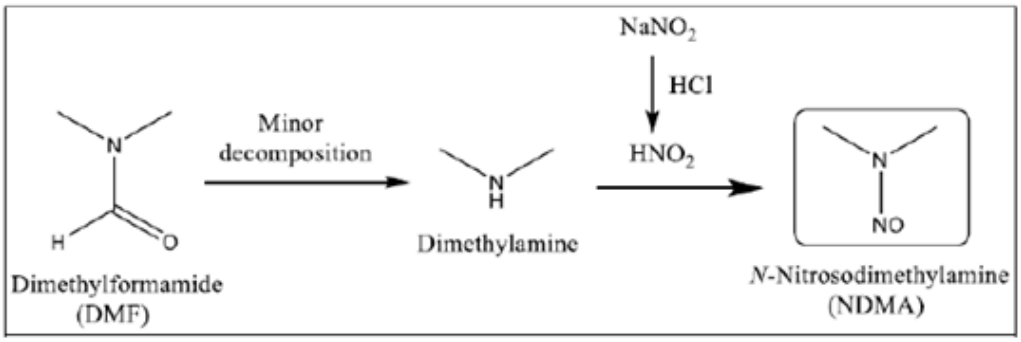
264. N-nitrosamines are formed as part of the synthetic process or through introduction of N-nitrosamines through use of recovered solvents.

265. As to the synthetic process, "formation of N-nitrosamines is only possible in the presence of a secondary or tertiary amine and nitrite, usually under acidic reaction conditions.[79]

266. NDMA is derived from the decomposition of dimethylformamide (DMF) at high temperatures to dimethylamine (DMA). DMA acts as the secondary amine leading to formation of NDMA, as shown in the following diagram:

[79] *Id.* at 5.

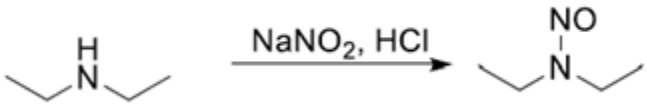
Fig.: 2 Formation of NDMA from DMF



267. DMA may also be present as an impurity in DMF as it is a precursor in the industrial DMF synthetic process, which can then lead to formation of NDMA in the ARB drugs. DMA "may also be a degradant formed during storage of the solvent, potentially present as the formate salt.[80]

268. NDEA is "generated from diethylamine (DEA) by analogy to the formation of NDMA from DMA," as depicted in the following diagram:[81]

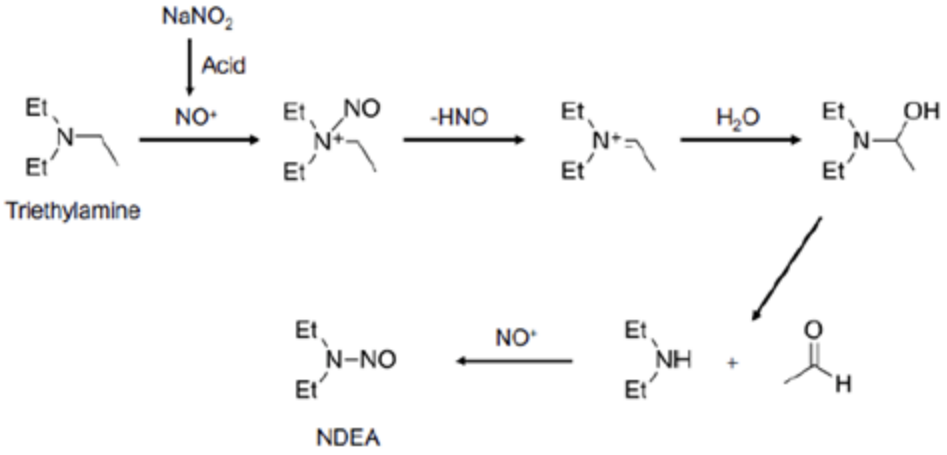
Fig.: 3 General reaction scheme for formation of NDEA from diethylamine



269. Alternatively, "direct nitrosation of TEA may occur via a nitrosoiminium ion, resulting in the generation of an aldehyde and a secondary amine, which reacts with further nitrous acid to form a nitrosamine."[82]

80 *Id.*
81 *Id.*
82 *Id.* at 6.

Fig. 4: Nitrosative cleavage of TEA to DEA followed by nitrosation to NDEA



270. Upon information and belief, the nitrosamine contamination in the LCDs is also the result of the API Manufacturer Defendants utilizing recycled or recovered solvents during the manufacture of the Active Pharmaceutical Ingredient ("API").

271. NMBA is "formed during the synthesis of losartan while using sodium nitrite and N-methylpyrrolidone."[83]

272. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.[84]

W. Recalls of ARB Drugs due to Nitrosamine Contamination

273. Recalls of ARB drugs due to nitrosamine contamination initially began after nitrosamine impurities were discovered in valsartan-containing drugs on or

83 *Id.* at 25.

84 http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf.

around July 13, 2018.[85] Since that time, the regulatory investigation has broadened to include other ARB drugs, including valsartan and losartan.

1. U.S. Valsartan Recalls

274. On July 13, 2018, the Food and Drug Administration announced a recall of certain batches of valsartan-containing drugs after finding NDMA in the recalled product. The products subject to this recall were some of those which contained the active pharmaceutical ingredient (API) supplied by Zhejiang Huahai Pharmaceuticals.[86] FDA further noted that the valsartan-containing drugs being recalled "does not meet our safety standards."[87]

275. The recall notice further stated, "Zhejiang Huahai Pharmaceuticals has stopped distributing its valsartan API and the FDA is working with the affected companies to reduce or eliminate the valsartan API impurity from future products."[88]

276. As of September 28, 2018, FDA placed Zhejiang Huahai Pharmaceuticals Co, Ltd. on import alerts, which halted all API made by the company from entering the United States. This was the product of an inspection of Zhejiang Huahai's facility.[89]

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85 https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan

86 https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.

87 https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.

88 https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.

89 https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM621162.pdf.

277. FDA's recall notice also stated that the presence of NDMA in the valsartan-containing drugs was "thought to be related to changes in the way the active substance was manufactured."[90]

278. The recall was limited to "all lots of non-expired products that contain the ingredient valsartan supplied to them by [the Active Pharmaceutical Manufacturer (API)] supplied by this specific company."

279. On July 18, 2018, FDA put out another press release about the recall, noting its determination that "the recalled valsartan products pose an unnecessary risk to patients."[91]

280. After the initial recall in July, 2018, the list of valsartan-containing medications discovered to contain NDMA continued to grow.

281. On August 9, 2018, FDA announced that it was expanding the recall to include valsartan-containing products manufactured by another API manufacturer, Hetero Labs Limited, labeled as Camber Pharmaceuticals, Inc., as these recalled pills also contained unacceptable levels of NDMA.[92] FDA noted, "Hetero Labs manufactures the API for the Camber products using a process similar to Zhejiang Huahai Pharmaceuticals."[93]

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90 https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
91 https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
92 https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
93 https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

282. On October 5, 2018, FDA posted the results of some testing conducted on samples of recalled valsartan tablets. Noting that "consuming up to 0.096 micrograms of NDMA per day is considered reasonably safe for human ingestion based on lifetime exposure," the results of the testing showed levels ranging from 0.3 micrograms up to 17 micrograms[94] (emphasis added). Thus, the pills contained somewhere between 3.1 and 177 times the level of NDMA deemed safe for human consumption. Subsequent testing revealed levels as high as 20 micrograms, which is 208.3 times the safe level.

283. By way of comparison, NDMA is sometimes also found in water and foods, including meats, dairy products, and vegetables. The U.S. Health Department set strict limits on the amount of NDMA that is permitted in each category of food, but these limits are dwarfed by the amount of NDMA present in the samples of the valsartan-containing medications referenced above. For example, cured meat is estimated to contain between 0.004 and 0.23 micrograms of NDMA.[95]

284. On November 21, 2018, FDA announced a new recall, this time because NDEA was detected in the tablets. Additional recalls of valsartan-containing tablets which were found to contain NDEA followed. These recall

94 https://www.fda.gov/Drugs/DrugSafety/ucm622717.htm

95 https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

notices also stated that the recalls related to unexpired valsartan-containing products.[96]

285. Over the course of the fall and winter of 2018, NDMA and NDEA continued to be detected across so many brands of valsartan and other ARB drugs that the FDA imposed interim limits for NDMA and NDEA in ARBs to prevent drug shortages. In doing so, FDA reminded "manufacturers that they are responsible for developing and using suitable methods to detect impurities, including when they make changes to their manufacturing processes. If a manufacturer detects a new impurity or high level of impurities, they should fully evaluate the impurities and take action to ensure the product is safe for patients.[97]

286. These recalls have continued through the first half of 2019 and may continue past the date this Complaint is filed.

2. Losartan Recalls

287. In December of 2018 Torrent recalled some of its losartan-containing drugs. Torrent expanded its recall of losartan-containing drugs in January, March, April and September of 2019. Defendant Torrent Pharmaceuticals purchased its API from Defendant Hetero Labs. Defendants AvKare, RemedyRepack, Inc. Preferred

96 https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm

97 https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

Pharmaceuticals, Inc. and Legacy Pharmaceutical Packaging, LLC are a few of the labelers and repackagers who get their losartan-containing drugs from Torrent.

288. On February 25, 2019, the Macleods Defendants recalled certain LCDs with API also purchased from Defendant Hetero Labs, Ltd.

289. On March 1, 2019, Defendant Hetero and its distributor, Camber, issued a recall for many of its LCDs. Defendant Camber supplied LCDs to both Legacy Pharmaceutical Packaging, LLC and HJ Harkins Co. d/b/a Pharm Pac.

290. On April 29, Defendant Teva also recalled LCDs and subsequently expanded its scope. The API in Teva's products was purchased from Defendant Hetero Labs, Ltd. Defendant Teva supplied LCDs to Defendant Golden State Medical Supply.

291. On May 6, 2019, Defendant Vivimed Life Sciences issued a recall. Defendant Vivimed's API was also sourced from Hetero Labs, Ltd. and was subsequently distributed, labeled, and/or packaged by Defendant Heritage Pharmaceuticals, Inc.

292. On October 8, 2019, FDA sent a Warning Letter to Torrent Pharmaceuticals, Limited, citing the company with numerous "significant" violations of cGMPs relating to their LCDs.[98] Specifically, FDA noted that Torrent

[98] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/torrent-pharmaceuticals-limited-585255-10082019

failed to follow its process validation protocol and after multiple batches of API failed tests, Torrent developed alternate protocols to "justify commercial use of the alternate API, even though [Torrent] had data demonstrating [its] process was not capable of producing quality material using the new alternate API."[99]

3. Recalls in Other Countries

293. The European Medicines Agency (EMA) also recalled many batches of valsartan-containing drugs. According to the agency, "[t]he review of valsartan medicines was triggered by the European Commission on 5 July 2018…On 20 September 2018, the review was extended to include medicines containing candesartan, irbesartan, losartan and olmesartan."[100]

294. Health Canada also issued a recall of valsartan-containing medications on July 9, 2018, noting the presence of NDMA as the reason. Health Canada similarly stated that NDMA is a potential human carcinogen.[101] Similarly, multiple batches of losartan[102] were subsequently recalled.

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99 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/torrent-pharmaceuticals-limited-585255-10082019

100 https://www.ema.europa.eu/en/medicines/human/referrals/angiotensin-ii-receptor-antagonists-sartans-containing-tetrazole-group.

101 http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67202a-eng.php#issue-problem.

102 https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/69272a-eng.php.

295. The contaminated LCDs consumed by Plaintiffs and manufactured, labeled, marketed, distributed, and/or sold by Defendants was not therapeutically equivalent to their RLDs, and was not manufactured in compliance with cGMPs.

296. Defendants illegally sold contaminated, adulterated LCDs to Plaintiffs.

297. As a result of the consumption of NDMA, NMBA or NDEA, Plaintiffs have been harmed, including, but not limited to, suffering cellular and genetic injury which creates and/or increases the risk that Plaintiffs will develop cancer.

298. Medical monitoring of Plaintiffs' conditions is necessary and required because of the nature of cancer, including the need for diagnosis and treatment as early as possible.

299. In the absence of medical monitoring to diagnose and treat cancer as early as possible, Plaintiffs and other Class Members are at an increased risk of suffering from the development and progression of cancer, with delayed diagnosis significantly increasing the risk of harm and death.

X. Defendants Had Actual and/or Constructive Notice of NDMA and/or NDEA Contamination of their Misbranded, Adulterated Drugs

300. The FDA has concluded that "NDMA and NDEA are probable human carcinogens and should not be present in drug products." As alleged above, the LCDs manufactured by the API and Finished Dose Manufacturer defendants were found to contain dangerously high levels of nitrosamines, including NDMA and NDEA, sometimes reaching levels higher than the FDA's interim safety limits.

301. NDMA and NDEA are not FDA-approved ingredients for the RLD, or their generic equivalents. Moreover, none of Defendants' LCDs identify NDMA, NDEA, NMBA or other nitrosamines as an ingredient on the products' labels or elsewhere. This is because these nitrosamines are probable human carcinogen active ingredients and are not approved to be included in LCDs. Their inclusion in Defendants' LCDs renders them misbranded and adulterated compared to Defendants' warranties and representations.

302. If Defendants had not routinely disregarded the FDA's cGMPs, including those discussed throughout this Complaint and the FDA's investigation reports and warning letter, and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have identified the presence of these nitrosamine contaminants almost immediately.

303. Most assuredly, NDMA, NMBA and NDEA are not FDA-approved ingredients for the RLD or their generic equivalents. None of Defendants' LCDs identifies NDMA, NMBA, NDEA, or any other nitrosamine as an ingredient on the products' labels or elsewhere. Their inclusion in Defendants' LCDs renders them misbranded and adulterated compared to Defendants' warranties and representations. Their inclusion in Defendants' LCDs renders them misbranded and adulterated compared to Defendants' warranties and representations.

304. If Defendants had not routinely disregarded the FDA's cGMPs and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have found the NDMA, NMBA and NDEA contamination almost immediately.

305. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

21 C.F.R. § 211.110(c).

306. And as shown above, Defendants' own quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by each API manufacturer.

307. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the nitrosamine contamination in Defendants' LCDs would have been discovered in 2012 (or perhaps earlier for other API manufacturers). Defendants were thus on (at minimum) constructive notice that their sartans were contaminated, adulterated, and/or misbranded as early as 2012.

308. And yet, Defendants knowingly, recklessly, and/or negligently introduced contaminated, adulterated, and/or misbranded LCDs containing dangerous amounts of nitrosamines into the U.S. market. Defendants failed to recall their LCDs because they feared permanently ceding market share to competitors. And Defendants issued the "voluntary" recall of their LCDs only after the FDA had threatened an involuntary recall.

Y. Other Contaminants

309. Testing and evaluation is ongoing of LCDs manufactured, distributed, or sold by Defendants. Besides NDMA, NMBA and NDEA, ongoing investigation suggests other impurities, may also exist as well in the LCDs at issue.

Z. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their LCDs

310. Each Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about their contaminated, adulterated, and/or misbranded LCDs.

311. The recalls were meant to quickly remove unsafe products from the market. While FDA advised patients to continue taking LCDs, it only did so as an interim measure because of a potential shortage of the medication and the risks associated with untreated high blood pressure.

312. In response to the recall, pharmacies and health care providers throughout the United States contacted affected patients to advise them of the recall

and to recommend that they contact their doctors to request a replacement or an alternative treatment option.

313. Because of the seriousness of the impurity—unsafe levels of a carcinogen— all or virtually all patients immediately stopped taking the tainted drug products after receiving notice of the recall. They were prescribed a safe alternative. LCDs had no use and were discarded.

AA. Fraudulent Concealment and Tolling

314. Plaintiffs' and Class Members' causes of action accrued, at the earliest, on the date the FDA announced the recall of Defendants' LCDs.

315. Alternatively, any statute of limitation or prescriptive period is equitably tolled on account of fraudulent concealment. Defendants each affirmatively concealed from Plaintiffs and other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge of their and other Defendants' cGMP violations with respect to their LCDs, and of the fact that their LCDs were adulterated and/or misbranded and contaminated with nitrosamines, and were not the same as their RLDs.

316. For instance, no Defendant revealed to the public that their LCDs contained nitrosamines or was otherwise contaminated, adulterated, misbranded, and/or unapproved, or non-therapeutically equivalent to their RLDs until the FDA's recall announcement. Inspection reports preceding recall announcement relating to

contamination was heavily redacted (including the names of the drugs affected by Defendants' cGMP violations), and prior inspection reports or warnings were not fully available to the public, if at all.

317. To the contrary, each Defendant continued to represent and warrant that their LCDs were the same as and therapeutically interchangeable with their RLDs.

318. Because of this, Plaintiffs and other Class Members did not discover, nor could they have discovered through reasonable and ordinarily diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations, lulled Plaintiffs and Class Members into believing that the purchase and use of their LCDs were appropriate for what they believed to be non-adulterated or misbranded drugs despite their exercise of reasonable and ordinary diligence.

319. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiffs and other Class Members has been tolled. Plaintiffs and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiffs were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

IV. CLASS ACTION ALLEGATIONS

320. Plaintiffs bring this action on behalf of themselves and, under Federal Rule of Civil Procedure 23(a), (b)(2), (b)(3), and (c)(4), as representatives of the classes defined as follows:

> All individuals residing in the United States of America and its territories and possessions who consumed generic losartan-containing drugs contaminated with NDMA, NMBA, NDEA, or other nitrosamine, manufactured by or for Defendants and marketed in the United States and its territories and possessions, since March 2012, when the FDA approved the first generic version of Cozaar and Hyzaar, the "Nationwide Class."

321. Excluded from the Nationwide Class, and from the other additional and alternative classes defined below, are Defendants and their subsidiaries and affiliates; all persons who make a timely election to be excluded from the Class or classes to the extent any class is an opt-out class or a hybrid opt-out class; governmental entities; and any judicial officers who preside over this case and their immediate family members. Also excluded from the Nationwide Class are those consumers of LCDs who have been diagnosed with cancers as a result of taking Defendants' NDMA-, NDEA-, or other nitrosamine-contaminated LCDs.

322. Plaintiffs allege additional classes for all individuals in each State, territory, or possession – or combination(s) of States, territories, or possessions to the extent class members from jurisdictions can be grouped together for purposes of class treatment – who, since March 2012 to the present, consumed LCDs

contaminated with NDMA, NMBA, NDEA, or other nitrosamine, manufactured by or for Defendants and marketed in the United States and its territories and possessions. These include but are not limited to the following:

Plaintiff Samuel Rivera seeks to represent a New Jersey class or class(es) of states with similar applicable laws to New Jersey.

Plaintiff Denice Gipson seeks to represent a Missouri class or class(es) of states with similar applicable laws to Missouri.

Plaintiff Samella Jackson seeks to represent a Arkansas class or class(es) of states with similar applicable laws to Arkansas.

Plaintiff Rick Monchamp seeks to represent a Arizona class or class(es) of states with similar applicable laws to Arizona.

323. Collectively, the foregoing Nationwide Class and its alternative classes are referred to as the "Class."

324. Plaintiffs reserve the right to narrow or expand the foregoing class definition, or create subclasses, in light of future fact discovery, and including as the Court deems necessary. These may include, by way of example, bellwether classes or state or other sub-classes.

A. The Classes Meet the Rule 23 Requirements

325. Plaintiffs meet the prerequisites of Rule 23(a), (b), and (c) to bring this action on behalf of the Class and Classes.

326. **Numerosity (Rule 23 (a)(1))**: While the exact number of Class Members cannot be determined without discovery, the proposed nationwide class potentially reaches the millions, and there is no proposed class with fewer than thousands or more of members. The Class Members are therefore so numerous that joinder of all members is impracticable as to the nationwide class and/or as to the subclasses.

327. **Commonality (Rule 23(a)(2))**: Even a single common question can drive a litigation and warrant certification. Here, material common questions of law and fact exist as to all Class Members, including but not limited to:

a. Whether each Defendant's LCDs were contaminated with NDMA, NMBA or NDEA and thus contaminated, adulterated, and/or misbranded;

b. Whether Defendants violated cGMPs regarding the manufacture of their LCDs;

c. Whether Defendants negligently or defectively manufactured the LCDs consumed by Plaintiffs and other Class Members;

d. Whether Defendants misrepresented facts or failed to warn as to the contamination;

e. Whether each Defendant made and breached express or implied warranties of "sameness" to Plaintiff and other Class Members regarding their LCDs, representing they were the same as their RLDs;

f. Whether each Defendant affirmatively misrepresented that its LCDs were the same as their RLDs and thus therapeutically interchangeable, or omitted the fact that it was not;

g. Whether each Defendant affirmatively misrepresented that it was compliant with cGMPs, or omitted the fact that it was not;

h. Whether Plaintiffs and other Class Members have suffered cellular and/or genetic injury and are at increased risk of developing cancer as a result of each Defendants' unlawful conduct;

i. Whether testing is available for the cancers to which Plaintiffs and the Class Members are at increased risk;

j. The nature and extent of medical monitoring, testing, examinations, and treatment necessary to address the risks created by Plaintiffs' and other Class Members' consumption of LCDs contaminated with NDMA or NDEA;

k. When Plaintiffs' and other Class Members' claims for relief accrued;

l. Whether Defendants fraudulently concealed Plaintiffs' and other Class Members' causes of action.

328. **Typicality (Rule 23(a)(3))**: Plaintiffs' claims are typical of Class Members' claims. Plaintiffs and other Class Members all suffered the same type of harm, including exposure to NDMA, NMBA and/or NDEA, cellular and/or genetic injury, cancer, and/or an increased risk of developing cancer, but have not yet been diagnosed with cancer. Plaintiffs bring claims under the same legal and remedial theories as the class. Plaintiffs' claims arise out of the same set of facts and conduct as all other Class Members.

329. **Adequacy of Representation (Rule 23(a)(4) and Rule(g))**: Plaintiffs are committed to pursuing this action and have retained competent counsel experienced in pharmaceutical and products liability litigation, medical monitoring, consumer litigation, and class actions. Accordingly, Plaintiffs and their counsel will fairly and adequately protect the interests of Class Members. Plaintiffs' claims are coincident with, and not antagonistic to, those of the other Class Members and Plaintiffs will fairly and adequately represent the interests of Class Members.

330. **Rule 23(b)(2):** Defendants have acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Classes as a whole.

331. **Rule 23(b)(3) Predominance and Superiority:** Here, the common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and a class action is the superior method for fair and efficient adjudication of the controversy. The likelihood that individual Class Members will prosecute separate actions for medical monitoring is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues is furthermore not efficient, timely or proper. Judicial resources will be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated plaintiffs. Plaintiffs' counsel, highly experienced in pharmaceutical and product liability litigation, consumer litigation, class actions, and federal court litigation, foresee the efficient management of this case as a class action.

332. **Rule 23(c)(4) Issues Class:** To the extent the Court determines there are material differences in the relevant laws and that such differences present class manageability issues precluding nationwide class certification for all purposes, Plaintiffs submit that a nationwide issue class is appropriate for determination of common material fact issues in the case, and are predicates for the entitlement to

medical monitoring (such as exposure, contamination, misconduct, increased risk, existence of testing and benefit of testing, among others).

V. CLAIMS FOR RELIEF

COUNT I
NEGLIGENCE
(Individually and on Behalf of the Class)

333. Plaintiffs repeat and reallege the preceding paragraphs as if fully set forth herein.

334. Each Defendant owed a duty to Plaintiffs and the Classes to use and exercise reasonable and due care in the manufacturing, testing, distribution, labeling, marketing, warnings, disclosures, and sale of its LCDs.

335. Each Defendant owed a duty to Plaintiffs and the Classes to ensure that the LCDs it sold in the United States were not contaminated with NDMA, NMBA or NDEA, contained only the ingredients stated in the label, were therapeutically equivalent to the brand drug, and/or complied with cGMPs, and/or were not contaminated or adulterated.

336. Each Defendant owed a duty of care to Plaintiffs and the Classes because they were the foreseeable, reasonable, and probable users of LCDs. Each Defendant knew, or should have known, that its LCDs products were contaminated with NDMA, NMBA and/or NDEA, did not contain only the ingredients stated, were not therapeutically equivalent to the brand drug and/or did not comply with cGMPs,

and/or were adulterated, and each was in the best position to uncover and remedy these shortcomings.

337. Defendants negligently manufactured the LCDs at issue, causing contamination with NDMA, NMBA and NDEA, which are carcinogens.

338. Each Defendant failed to fulfill its duty of care. Each Defendant inadequately conducted or oversaw the manufacture, testing, labeling, distribution, marketing, warnings, disclosures, and sale of the LCDs at issue. Each Defendant knew that the aforesaid wrongdoing would damage Plaintiffs and other Class Members.

339. Each Defendant negligently failed to promptly and immediately warn and disclose to Plaintiffs and other Class Members, and the medical and regulatory communities, of the potential and actual contamination with NDMA, NMBA and/or NDEA as soon as it was discovered, delaying notice of this harmful and potentially fatal toxic exposure to a carcinogen and thus causing continued exposure to the carcinogenic contamination, and delaying necessary testing, examinations, surveillance, and treatment.

340. Defendants' negligent conduct created and then exacerbated an unreasonable, dangerous condition for Plaintiffs and other Class Members.

341. Defendants acted with recklessness and willful and wanton disregard for the health of Plaintiffs and other Class Members.

342. Each Defendant's own unreasonable, negligent actions and inactions were taken or not taken with willful and wanton disregard for the health of Plaintiffs and other Class Members and created a foreseeable risk of harm to Plaintiff and other Class Members.

343. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and other Class Members have suffered cellular and genetic injury that creates and/or increases the risk that Plaintiffs will develop cancer, necessitating notice to all Class Members, sufficient funding for the tests and evaluations of each Class Member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

344. Plaintiffs and Class Members seek compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA, NMBA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to

provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

COUNT II
NEGLIGENCE PER SE
(Individually and on Behalf of the Class)

345. Plaintiffs reallege and incorporate the preceding paragraphs as if fully set forth herein.

346. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacture of its LCDs.

347. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the LCDs it sold in the United States were therapeutically equivalent to the brand-name drug and complied with cGMPs and were not adulterated or misbranded.

348. Each Defendant owed a duty to Plaintiffs and the Class because each state, territory, and possession has adopted /or adheres to federal cGMP and adulteration standards.

349. Each Defendant failed to comply with federal cGMPs and federal adulteration standards.

350. Each Defendant's own actions and inactions created a foreseeable risk of harm to the Plaintiffs and to the Class.

351. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and other Class Members have suffered cellular and genetic injury which

creates and/or increases the risk that Plaintiffs will develop cancer, necessitating notice to all Class Members, sufficient funding for the tests and evaluations of each Class Member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

352. Plaintiffs and Class Members seek compensatory damages for, and the creation of a fund to adequately finance the costs of, the creation of a fund to adequately finance the costs of medical monitoring procedures (1) to notify and alert all people exposed to NDMA, NMBA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

COUNT III
MEDICAL MONITORING
(Individually and on Behalf of the Class)

353. Plaintiffs repeat and reallege the preceding paragraphs as if fully set forth herein.

354. As a proximate result of Defendants' acts and omissions, the Class is at an increased risk of developing cancer above the normal base-level risk.

355. As alleged above, Defendant's Losartan product was contaminated with NDMA, NMBA and/or NDEA, agents known to cause cancer in humans.

356. The Class Members may not develop cancer for many years.

357. The Class Members are at an increased risk as they consumed and/or ingested Defendants' LCDs for extended periods of time, some as many as several years, and as a result were exposed to a contaminant.

358. Upon information and belief, and based upon the internal and external investigations now made public, the Class is at an increased risk as they were exposed to NDMA, NMBA and/or NDEA.

359. NDMA, NMBA and NDEA are hazardous, life-threatening, toxic substances that are known to cause cancer in humans.

360. The Class Members are at an increased risk of cancer as they were exposed to, consumed, and/or ingested Defendants' LCDs in quantities, and over periods of time sufficient to establish an exposure level that is considered to be hazardous to health, and that is considered to be sufficient to cause cancer or increase the risk of developing cancer.

361. The exposure was caused solely and proximately by Defendants' failure to adequately manufacture their LCDs to be therapeutically equivalent to the

brand drug; their failure to address discrepancies in batches/doses of LCDs during quality control testing; their material misrepresentations, false statements, and other deceptive practices in continuing to claim that their LCDs were safe for consumption and/or ingestion and therapeutically equivalent to the brand drug.

362. Defendants had a duty to the Class Members to: ensure and warrant that their LCDs were indeed therapeutically equivalent to the brand-name drug as claimed and advertised to the Class Members; to disclose to the Class Members any defect, contamination, impurity or other potential health hazard known or discoverable by Defendants; and to ensure that their LCDs were safe, reliable, and non-hazardous for human consumption—its intended purpose.

363. As alleged above, Defendants' own negligent acts and omissions resulted an increased risk of developing cancer for all members of the Class. Cancer is a serious disease-causing life-threatening illness and debilitating cellular, genetic, and physical injury. Technology, analytical tools, tests and/or monitoring procedures exist and are readily available to provide for the testing and early detection of cancer in patients. These technologies, tools, tests and/or monitoring procedures are accepted and widely used by the scientific and medical community. These existing scientific methods include, but are not limited to, guaiac-based fecal occult blood test (gFOBT), fecal immunochemical test (FIT), FIT-DNA test, Flexible Sigmoidoscopy, Colonoscopy, and CT Colonography (Virtual Colonoscopy).

364. Early detection of cancer in patients is one of the best, and sometimes the only means to treat cancer such that it does not cause lasting, permanent injury, illness, or death.

365. Early detection of cancer in patients necessarily allows patients to avail themselves of myriad forms of treatment, each of which is capable of altering the course of the illness, such as bringing the cancer into remission, removal of any malignant tumors, and other treatment to alleviate injury.

366. The tests and treatments for the early detection and treatment of cancer must be prescribed by a qualified physician, and are conducted according to the latest, contemporary, and widely accepted scientific principles. Because NDMA/NMBA/NDEA -associated cancer screenings may not be conducted with the frequency necessary to identify cancer in the absence of exposure to NDMA/NMBA/NDEA, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Plaintiff and Class Members require more frequent screenings not within the purview of routine medical exams.

367. The facts alleged above are sufficient or more than sufficient to plead a claim for medical monitoring as a cause of action.

368. Plaintiffs seek, on behalf of themselves and the Class Members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical

monitoring procedures (1) to notify and alert all people exposed to NDMA, NMBA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

COUNT IV
PRODUCTS LIABILITY-MANUFACTURING DEFECT
(Individually and on Behalf of the Class)

369. Plaintiffs repeat and reallege the preceding paragraphs as if fully set forth herein.

370. The LCDs at issue were defectively manufactured, as the manufacturing process caused it to be contaminated by NDMA, NMBA and NDEA.

371. LCDs contaminated with NDMA, NMBA and/or NDEA is by definition defectively manufactured.

372. Defendants' conduct in defectively manufacturing LCDs was reckless and taken with wanton and willful disregard for the health of Plaintiffs and other Class Members.

373. Defendants are strictly liable for the harm caused by or contributed to by the defectively manufactured LCDs.

374. As a direct and proximate result, Plaintiffs and other Class Members have been injured and suffered damages, in that LCDs they consumed were contaminated with NDMA, NMBA or NDEA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

375. Plaintiffs seek, on behalf of themselves and the Class Members, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA, NMBA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to

provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

COUNT V
FAILURE TO WARN
(Individually and on Behalf of the Class)

376. Plaintiffs repeat and reallege the preceding paragraphs as if fully set forth herein.

377. Defendants failed to warn Plaintiffs and the Class Members, and the medical and regulatory communities, of the potential or actual contamination of the LCDs with NDMA, NMBA and NDEA, as soon as this was suspected or known.

378. Defendants' failure to warn was intentional, reckless, and in wanton and willful disregard for the rights and health of Plaintiffs and other Class Members, causing exposure to carcinogens and delay of diagnosis and treatment.

379. Defendants are strictly liable for their failure to warn or adequately disclose information.

380. As a direct and proximate result of each Defendant's failure to warn or disclose information, Plaintiffs and other Class Members have been injured and suffered damages, in that the Defendants' LCDs that they consumed were contaminated with NDMA, NMBA or NDEA and thus created and/or increased the risk that Plaintiffs and other Class members will develop cancer.

381. Plaintiffs seek, on behalf of themselves and the Class Members, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA, NMBA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

COUNT VI
VIOLATION OF THE MAGNUSON-MOSS WARRANTY ACT
15 U.S.C. § 2301 *et seq.*
(Individually and on Behalf of the Class)

382. Plaintiffs repeat and re-allege the preceding paragraphs as if fully set forth herein.

383. Plaintiffs bring this Count on behalf of members of the Classes who are residents of the following States: Alaska, Arkansas, California, Colorado, Delaware, District of Columbia, Hawaii, Indiana, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska,

Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Utah, Virginia, West Virginia and Wyoming.

384. This Court has jurisdiction to decide claims brought under 15 U.S.C. § 2301 by virtue of 28 U.S.C. § 1332 (a)-(d).

385. The contaminated doses of LCDs are "consumer products" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(1).

386. Plaintiffs are "consumers" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(3). They are consumers because they are persons entitled under applicable state law to enforce against the warrantor the obligations of its express and implied warranties.

387. Defendants were "supplier[s]" and "warrantor[s]" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(4)-(5).

388. 15 U.S.C. § 2310(d)(1) provides a cause of action for any consumer who is damaged by the failure of a warrantor to comply with a written or implied warranty.

389. Defendants provided Plaintiffs and the other Class members with an implied warranty of merchantability in connection with the purchase of LCDs that is an "implied warranty" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(7). As a part of the implied warranty of merchantability,

Defendants warranted that the LCDS ultimately found to be contaminated with NDMA, NMBA and/or NDEA was fit for its ordinary purpose as a safe pharmaceutical medication, would pass without objection in the trade as designed, manufactured, and marketed, and were adequately contained, packaged, and labeled. N.J. Stat. Ann. § 12A:2-314(2)(a), (c), and (e); U.C.C. § 2-314.

390. Defendants breached these implied warranties, as described in more detail above, and are therefore liable to Plaintiffs and the Class pursuant to 15 U.S.C. § 2310(d)(1). Without limitation, doses and/or batches of contaminated LCDs share common design defects in that they have caused cellular and/or genetic injury, cancer, or an increased risk of developing cancer.

391. In their capacity as warrantors, Defendants had knowledge of the defects in the batches of LCDs they manufactured, distributed, and sold, any efforts to limit the implied warranties in a manner that would exclude coverage of contaminated LCDs is unconscionable, and any such effort to disclaim, or otherwise limit, liability for contaminated LCDs is null and void.

392. Privity is not required here because Plaintiffs and each of the other Class members are intended third-party beneficiaries of any contracts between Defendants and their distributors, and specifically, of the implied warranties. The distributors were not intended to be the ultimate consumers of LCDs and have no rights under the warranty agreements provided with each container of LCDs; the

warranty agreements were designed for and intended to benefit consumers. Finally, privity is also not required because the contaminated batches and/or doses of LCDs are dangerous instrumentalities due to the aforementioned defects and nonconformities. In the alternative, to the extent it is required, it is satisfied.

393. Pursuant to 15 U.S.C. § 2310(e), Plaintiffs are entitled to bring this class action and are not required to give Defendants notice and an opportunity to cure until such time as the Court determines the representative capacity of Plaintiffs pursuant to Rule 23 of the Federal Rules of Civil Procedure.

394. Furthermore, affording Defendants an opportunity to cure their breach of written warranties would be unnecessary and futile here. At the time of sale of each batch and/or dose of contaminated LCDs Defendants knew, should have known, or were reckless in not knowing of their misrepresentations concerning the contamination of the LCDs and failure to perform as warranted, but nonetheless failed to rectify the situation and/or disclose the contamination.

395. Plaintiffs seek injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA, NMBA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies,

and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

COUNT VII
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(Individually and on Behalf of the Class)

396. Plaintiffs repeat and reallege the preceding paragraphs as if fully set forth herein.

397. Defendants are merchants with respect to LCDs within the laws of each jurisdiction.

398. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann.

§ 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

399. Each Defendant was a merchant within the meaning of the above statutes.

400. Each Defendant's LCDs constituted "goods" or the equivalent within the meaning of the above statutes.

401. Each Defendant was obligated to provide Plaintiffs and other Class Members reasonably fit LCDs for the purpose for which the products were sold, and to conform to the standards of the trade in which Defendants are involved such that

the products were not contaminated with a carcinogen and were of fit and merchantable quality.

402. Each Defendant knew or should have known that its LCDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to the brand drug (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that their LCDs were of merchantable quality and fit for that purpose.

403. Each Defendant breached its implied warranty because each Defendant's LCDs were contaminated with a carcinogen and not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

404. Defendants were provided notice of these issues by numerous discrepancies in quality control testing results, evidence of contaminants in analyses of batches/doses of LCDs, investigations conducted internally and by the FDA and communications sent by the Class before or within a reasonable amount of time after Defendants knew, or reasonably should have known of the foregoing.

405. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that LCDs manufactured by the defendants that they consumed were

contaminated with NDMA, NMBA or NDEA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

406. Plaintiffs seek injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA, NMBA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

COUNT VIII
BREACH OF EXPRESS WARRANTIES
(Individually and on Behalf of the Class)

407. Plaintiffs repeat and reallege the preceding paragraphs as if fully set forth herein.

408. Each Defendant expressly warranted that its LCDs were fit for their ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically

identical to and interchangeable with their RLDs. In other words, Defendants expressly warranted that their products were the same as their RLDs.

409. Each Defendant sold LCDs that they expressly warranted were compliant with cGMP and/or not adulterated and/or misbranded.

410. Each Defendant's LCDs did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and/or was adulterated and/or misbranded.

411. At all times relevant, all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann.

§ 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

412. At the time that each Defendant marketed and sold its LCDs, it recognized the purposes for which the products would be used, and expressly warranted the products were the same as their RLDs, and cGMP compliant and/or not adulterated and/or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs and other Class Members, including but not limited to express representations made in referring to their LCDs as Losartan.

413. Each Defendant breached its express warranties with respect to its LCDs as it was contaminated and not of merchantable quality, was not fit for its ordinary purpose, and did not comply with cGMP and/or was adulterated and/or misbranded.

414. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that the Defendants' LCDs they consumed were contaminated with NDMA, NMBA or NDEA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

415. Plaintiffs seek injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA, NMBA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

COUNT IX
VIOLATIONS OF STATE CONSUMER PROTECTION LAWS
(Individually and on Behalf of the Class)

416. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

417. This cause of action is alleged on behalf of Class Members against all Defendants.

418. Each Defendant has violated the consumer protection statutes as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, et seq.;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, et seq.;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, et seq.;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, et seq.;

e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, et seq.;

f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, et seq.;

g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, et seq.;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, et seq.;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, et seq.;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, et seq.;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, et seq.;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, et seq.;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, et seq.;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, et seq.;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, et seq.;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, et seq.;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, et seq.;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, et seq.;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, et seq.;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, et seq.;

Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, et seq.;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, et seq.;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, et seq.;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, et seq.;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, et seq.;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, et seq.;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, et seq.;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, et seq.;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, et seq.;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, et seq.;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, et seq.;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, et seq.;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, et seq.;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, et seq.;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, et seq.;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, et seq.

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, et seq.;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, et seq.;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, et seq.;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, et seq.;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, et seq.;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, et seq.;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, et seq.;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, et seq.;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, et seq.;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, et seq.;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, et seq.;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, et seq.; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, et seq.;

vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, et seq.;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, et seq.; and

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, et seq., the applicable statute for the Commonwealth of Puerto Rico.

419. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

420. Each Plaintiff and other Class Member is a consumer or person aggrieved by Defendants' misconduct within the meaning of the above statutes.

421. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages– an ascertainable loss – in an amount to be proved at trial.

COUNT X
FRAUD/FRAUDULENT CONCEALMENT
(Individually and on Behalf of the Class)

422. Plaintiffs repeat and reallege the preceding paragraphs as is fully set forth herein.

423. This claim is brought on behalf of the Nationwide Class or, alternatively, under the laws of all states, as there is no material difference in the law of fraud and fraudulent concealment as applied to the claims and questions in this case.

424. Defendants each concealed and suppressed material facts concerning the batches/doses of LCDs they manufactured, distributed, and sold, that were later found to be contaminated with NDMA/NMBA/NDEA.

425. As described above, Defendants each made material omissions and affirmative misrepresentations regarding the batches/doses of LCDs they manufactured, distributed, and sold.

426. The Defendants each knew these representations were false when made.

427. LCDs purchased by Plaintiffs was, in fact, contaminated, hazardous, a health hazard, unsafe and unreliable, because the LCDs manufactured by Defendants had not been properly manufactured nor properly tested for quality, and were later found to be contaminated with known carcinogens NDMA/NMBA/NDEA.

428. The Defendants each had a duty to disclose that the LCDs they manufactured, distributed, and sold, had been contaminated with NDMA/NMBA/NDEA, had demonstrated such contamination and other analytical discrepancies when it underwent quality control, and that consequent to that contamination, those batches/doses of LCDs were potentially hazardous to the Class Members' health and were unsafe for human consumption or ingestion. Plaintiffs relied on Defendants' representations that the LCDs they were purchasing and ingesting were safe and free from contamination.

429. The aforementioned concealment was material, because if it had been disclosed Plaintiffs would not have purchased or otherwise obtained LCDs from Defendants.

430. The aforementioned representations were also material because they were facts that would typically be relied on by a person purchasing or obtaining LCDs. The Defendants each knew or recklessly disregarded that their representations were false because they knew that the LCDs they were manufacturing, distributing, and selling were contaminated with NDMA/NMBA/NDEA, a substance known to cause cancer and/or increase the risk of cancer. The Defendants each intentionally made the false statements in order to sell LCDs and avoid the expense and public relations nightmare of a recall.

431. Plaintiffs relied on the Defendants' reputation, along with their failure to disclose the contamination of LCDs and manufacturing and quality control problems, and the Defendants' affirmative assurances that their LCDs were safe for human consumption and/or ingestion.

432. However, Defendants each concealed and suppressed material facts concerning obligations to monitor and test their products.

433. Further, Defendants each had a duty to disclose the true facts about the contaminated LCDs because they were known and/or accessible only to Defendants

who had superior knowledge and access to the facts, and the facts were not known to or reasonably discoverable by Plaintiffs and the Classes.

434. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' LCDs they consumed were contaminated with NDMA, NMBA or NDEA and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.

435. As a result of the fraud, Plaintiffs have suffered direct and consequential damages, and they seek recovery of those damages, and the creation of a fund to adequately finance the costs of medical monitoring procedures (1) to notify and alert all people exposed to NDMA, NMBA or NDEA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following judgment:

1. Certifying this Action as a class action;

2. Appointing Plaintiff(s) as Class Representative(s), and appointing undersigned counsel as Class Counsel to represent the Class;

3. A finding that Defendants are liable pursuant to each and every one of the above-enumerated causes of action;

4. Awarding appropriate preliminary and/or final injunctive relief;

5. Directing the Defendants to fund medical monitoring in an amount sufficient to fund necessary notice and medical care, including but not limited to examinations, tests, pathology, blood tests, evaluations, and treatment, as necessary and appropriate;

6. Payment to Plaintiff and other Class Members of compensatory damages necessary for their monitoring and care;

7. An award of attorneys' fees and costs;

8. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest; and

9. Such other and further relief as this Court may deem equitable and just.

JURY DEMAND

Plaintiffs respectfully request a trial by jury on all causes of action so triable.

Dated: December 18, 2020

Respectfully Submitted,

/s/ Ruben Honik
Ruben Honik
GOLOMB & HONIK, P.C.
1835 Market Street, Ste. 2900
Philadelphia, PA 19103
Phone: (215) 985-9177
rhonik@golombhonik.com

/s/ Daniel Nigh
Daniel Nigh
LEVIN, PAPANTONIO, THOMAS,
MITCHELL RAFFERTY & PROCTOR, P.A.
316 South Baylen Street
Pensacola, FL 32502
Phone: (850) 435-7013
dnigh@levinlaw.com

/s/ Adam Slater
Adam Slater
MAZIE, SLATER, KATZ & FREEMAN, LLC
103 Eisenhower Pkwy, 2nd Flr.
Roseland, NJ 07068
Phone: (973) 228-9898
aslater@mazieslater.com

/s/ Conlee S. Whiteley
Conlee S. Whiteley
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504)-524-5777
c.whiteley@kanner-law.com

MDL Plaintiffs' Co-Lead Counsel